

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
93NOD9WBCS	2-ethylhexyl-4-phenylbenzophenone-2-carboxylic acid	sunscreen		II	I		58 FR 28281
362O9ITL9D	acetaminophen	internal analgesic		I	I		
362O9ITL9D	acetaminophen	menstrual/diuretic	analgesic	I			
362O9ITL9D	acetaminophen	nighttime sleep aid		II	I		54 FR 6826
362O9ITL9D	acetaminophen	overindulgence in alcohol	hangover reliever	I			
SP86R356CC	acetanilide	internal analgesic		II	I		
Q40Q9N063P	acetic acid	otic				310.545(a)(15)(i)	
Q40Q9N063P	acetic acid	wart remover		III	II		[55 FR 33254]
Q40Q9N063P	acetic acid, glacial	corn/callus remover		II	II		[55 FR 33254]
Q40Q9N063P	acetic acid, glacial	wart remover		III	II		[55 FR 33254]
1364PS73AF	acetone	skin protectant	astringent	II		310.545(a)(18)(ii)	
	acidulated phosphate fluoride	anticaries			I	355.10(a)(3)(i)	
	acidulated phosphate fluoride	anticaries			I	355.10(a)(3)(ii)	
	agar	laxative	bulk laxative	III		310.545(a)(12)(i)	
18B8O9DQA2	alcloxa	acne		II	II	310.545(a)(1)	
18B8O9DQA2	alcloxa	anorectal	keratolytic	I(e)	I(e)	346.20(a)	
18B8O9DQA2	alcloxa	antifungal		III	III	310.545(a)(22)(ii)	
3K9958V90M	alcohol	digestive aid				310.545(a)(8)(ii)	
3K9958V90M	alcohol	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
3K9958V90M	alcohol	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
3K9958V90M	alcohol	menstrual/diuretic				310.545(a)(24)(i)	
3K9958V90M	alcohol	mercury			I		
3K9958V90M	alcohol	oral health care		III	II		
3K9958V90M	alcohol	skin protectant	astringent	II		310.545(a)(18)(ii)	
3K9958V90M	alcohol	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
3K9958V90M	alcohol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
3K9958V90M	alcohol	skin protectant		II	II		
3K9958V90M	alcohol	weight control			II	310.545(a)(20)	
3K9958V90M	alcohol, ethoxylated alkyl	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
3K9958V90M	alcohol, ethoxylated alkyl	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
8T66131YNK	aldioxa	skin protectant	diaper rash		II		
SQI2NBY9KR	alfalfa	weight control			II	310.545(a)(20)	
SQI2NBY9KR	alfalfa leaves	menstrual/diuretic				310.545(a)(24)(i)	
8C3Z4148WZ	alginic acid	weight control		III		310.545(a)(20)	
	alkyl dimethyl amine oxide and alkyl dimethyl glycine	gingivitis/plaque		II	II		
	alkyl isoquinolinium bromide	acne		II		310.545(a)(1)	
	alkyl isoquinolinium bromide	dandruff		III	III	310.545(a)(7)	
344S277G0Z	allantoin	dandruff		III	III	310.545(a)(7)	
344S277G0Z	allantoin	external analgesic			II		
344S277G0Z	allantoin	skin protectant		I	I	347.10(a)	
344S277G0Z	allantoin (5-ureidohydantoin)	corn/callus remover		II	II		[55 FR 33261]

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
344S277G0Z	allantoin (with aminobenzoic acid)	sunscreen		II	III		58 FR 28281
344S277G0Z	allantoin (wound healing claims only)	skin protectant			III	310.545(a)(18)(i)(A)	
BN34FX42G3	allyl isothiocyanate	cough/cold	nasal decongestant			310.545(a)(6)(ii)(A)	
BN34FX42G3	allyl isothiocyanate	external analgesic	counterirritant	I	I	pending	
BN34FX42G3	allyl isothiocyanate	external analgesic	fever blister/cold sore		II	310.545(a)(10)(v)	
9104833TPA	almadrate sulfate	digestive aid	antacid	III	I		
V5VD430YW9, ZY	aloe ingredients (aloe, aloe extract, aloe flower extract)	laxative	stimulant laxative		I	310.545(a)(12)(iv)(C)	
09TD8L5SQV	aloe vera [see aloe]	gingivitis/plaque			III		
V5VD430YW9	aloes	menstrual/diuretic				310.545(a)(24)(i)	
W41H6S09F4	aloin	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
	alpha cellulose	laxative	bulk laxative		III		
DPU64XYB1D	alum, ammonium	oral health care	astringent	I	I		
DPU64XYB1D	alum, ammonium	skin protectant	astringent	II		310.545(a)(18)(ii)	
1L24V9R23S	alum, potassium	antifungal		III	III	310.545(a)(22)(ii)	
1L24V9R23S	alum, potassium	antiperspirant		II	II	310.545(a)(4)(i)	
1L24V9R23S	alum, potassium	oral health care			I		
1L24V9R23S	alum, potassium	skin protectant	astringent	II		310.545(a)(18)(ii)	
LMI26O6933	alumina powder, hydrated	antidiarrheal		III	III		
80EHD8I43D	aluminum acetate	external analgesic			I	347.12(a)	
80EHD8I43D	aluminum acetate	skin protectant	astringent	I	I	347.12(a)	
80EHD8I43D	aluminum acetate	skin protectant	diaper rash		II		
	aluminum bromohydrate	antiperspirant		II	II	310.545(a)(4)(i)	
	aluminum carbonate gel (basic)	antacid			I	331.11(a)(1)	
	aluminum chlorhydroxy complex	skin protectant	astringent	II		310.545(a)(18)(ii)	
LIF1N9568Y	aluminum chloride (alcoholic solutions)	antiperspirant		II	II	310.545(a)(4)(i)	
LIF1N9568Y	aluminum chloride (aqueous solution) (aerosol only)	antiperspirant				310.545(a)(4)(i)	
LIF1N9568Y	aluminum chloride (nonaerosol aqueous solution)	antiperspirant		I	I	350.10(a)	
LIF1N9568Y	aluminum chloride hexahydrate	external analgesic			III		
HPN8MZM13M	aluminum chlorhydrate	antiperspirant		I	I	350.10(b)	
	aluminum chlorhydrrex	acne		II	II	310.545(a)(1)	
	aluminum chlorhydrrex polyethylene glycol	antiperspirant		I	I	350.10(c)	
	aluminum chlorhydrrex propylene glycol	antiperspirant		I	I	350.10(d)	
	aluminum dichlorhydrate	antiperspirant		I	I	350.10(e)	
	aluminum dichlorhydrrex polyethylene glycol	antiperspirant		I	I	350.10(f)	
	aluminum dichlorhydrrex propylene glycol	antiperspirant		I	I	350.10(g)	
5QB0T2IUN0	aluminum hydroxide	acne		II	II	310.545(a)(1)	
5QB0T2IUN0	aluminum hydroxide	antacid			I	331.11(a)(2)	
5QB0T2IUN0	aluminum hydroxide	antidiarrheal				310.545(a)(3)(i)	
5QB0T2IUN0	aluminum hydroxide	digestive aid	antacid	III	I	310.545(a)(8)(ii)	
5QB0T2IUN0	aluminum hydroxide	overindulgence in alcohol	hangover reliever		I		
5QB0T2IUN0	aluminum hydroxide	skin protectant	diaper rash			310.545(a)(18)(iii)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
5QB0T2IUN0	aluminum hydroxide	skin protectant	diaper rash			310.545(a)(18)(iii)	
5QB0T2IUN0	aluminum hydroxide	topical analgesic	diaper rash			310.545(a)(10)(iv)	
5QB0T2IUN0	aluminum hydroxide gel	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(1)	
5QB0T2IUN0	aluminum hydroxide gel	overindulgence in alcohol	hangover reliever		I		
5QB0T2IUN0	aluminum hydroxide gel	skin protectant		I	I	347.10(b)	
5QB0T2IUN0	aluminum hydroxide-hexitol, stabilized polymer	antacid			I	331.11(a)(2)	
5QB0T2IUN0	aluminum hydroxide-magnesium carbonate, co-dried gel	antacid			I	331.11(a)(2)	
5QB0T2IUN0	aluminum hydroxide-magnesium trisilicate, co-dried gel	antacid			I	331.11(a)(2)	
5QB0T2IUN0	aluminum hydroxide-sucrose powder hydrated	antacid			I	331.11(a)(2)	
F92V3S5210	aluminum phosphate	antacid			I	331.11(i)(1)	
F92V3S5210	aluminum phosphate gel (in combination only)	antacid			I	331.11(a)(4)	
UCN889409V	aluminum sesquichlorohydrate	antiperspirant		I	I	350.10(h)	
	aluminum sesquichlorohydrate poylethylene glycol	antiperspirant			I	350.10(i)	
	aluminum sesquichlorohydrate propylene glycol	antiperspirant			I	350.10(j)	
34S289N54E	aluminum sulfate	antifungal				310.545(a)(22)(ii)	
34S289N54E	aluminum sulfate	antiperspirant		IISE	IIISE	310.545(a)(4)(i)	
	aluminum sulfate buffered w/ sodium aluminum lactate	antiperspirant	w/ sales less than \$25,000	I	IIIS	310.545(a)(4)(ii)	
I7T908772F	aluminum sulfate, anhydrous	skin protectant	astringent	I	I	347.12(b)	
	aluminum sulfate, buffered (aerosol only)	antiperspirant		I	IIIS	310.545(a)(4)(i)	
481Y8HDW2B	aluminum zirconium octachlorohydrate	antiperspirant		I	IIS	350.10(k)	
P9D3YP29MY	aluminum zirconium octachlorohydrex gly	antiperspirant		I	IIS	350.10(l)	
15K31617MU	aluminum zirconium pentachlorohydrate	antiperspirant		I	IIS	350.10(m)	
94703016SM	aluminum zirconium pentachlorohydrex gly	antiperspirant		I	IIS	350.10(n)	
8O386558JE	aluminum zirconium tetrachlorohydrate	antiperspirant		I	IIS	350.10(o)	
8O386558JE	aluminum zirconium tetrachlorohydrex gly	antiperspirant		I	IIS	350.10(p)	
T27D6T99LH	aluminum zirconium trichlorohydrate	antiperspirant		I	IIS	350.10(q)	
T27D6T99LH	aluminum zirconium trichlorohydrex gly	antiperspirant		I	IIS	350.10(r)	
376KTP06K8	amiloxate (isoamyl p-methoxycinnamate)	sunscreen		NA			
OR5RM3Q5QL	aminacrine hydrochloride	boil treatment			IISE	310.531(a)	
TE7660XO1C	aminoacetic acid	antiemetic			II		
TL2TJE8QTX	aminobenzoic acid	internal analgesic		II	II	310.545(a)(23)(i)	
TL2TJE8QTX	aminobenzoic acid (PABA)	sunscreen		I	I	352.10(a)	
27Y3KJK423	aminophylline	cough/cold	bronchodilator	I	II	310.545(a)(6)(iv)	
5138Q19F1X	ammonia solution, strong	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
5138Q19F1X	ammonia solution, strong (ammonia water, strong)	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
JD546Z56F0	ammoniated mercury	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
R0JB3224WS	ammonium bromide	nighttime sleep aid	bromide	II	IISE		[54 FR 6826]
R0JB3224WS	ammonium chloride	cough/cold	expectorant		III	310.545(a)(6)(iii)	
R0JB3224WS	ammonium chloride	menstrual/diuretic	diuretic	I	I		
R0JB3224WS	ammonium chloride	nighttime sleep aid			II		
R0JB3224WS	ammonium chloride	oral health care	expectorant	III			

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
R0JB3224WS	ammonium chloride	stimulant			IIE		[39 FR 6104]
5138Q19F1X	ammonium hydroxide	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
YOJ58O116E	amylase	digestive aid				310.545(a)(8)(ii)	
	amyltricresols, secondary	antifungal		III	III	310.545(a)(22)(ii)	
	amyltricresols, secondary	oral health care			IIIE		
	anion and cation exchange resins buffered	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
6Y89129C8H	anise oil	weight control			II	310.545(a)(20)	
21C2F5E8RE	anise seed	digestive aid				310.545(a)(8)(ii)	
DL6OZ476V3	antimony potassium tartrate	cough/cold	expectorant		II	310.545(a)(6)(iii)	
T3CHA1B51H	antipyrine	internal analgesic			III	310.545(a)(23)(i)	
T3CHA1B51H	antipyrine	ophthalmic	anesthetic		II	310.545(a)(21)(i)	
T3CHA1B51H	antipyrine	oral health care	anesthetic/analgesic		II	310.545(a)(14)	
7C0697DR9I	any atropine ingredient	internal analgesic				310.545(a)(23)(ii)	
7C0697DR9I	any atropine ingredient	menstrual/diuretic				310.545(a)(24)(ii)	
GN83C131XS	any ephedrine ingredient	internal analgesic				310.545(a)(23)(ii)	
GN83C131XS	any ephedrine ingredient	menstrual/diuretic				310.545(a)(24)(ii)	
94ZLA3W45F	arginine	weight control			II	310.545(a)(20)	
	aromatic powder	digestive aid				310.545(a)(8)(ii)	
	aromatics	skin protectant	astringent	II		310.545(a)(18)(ii)	
W9FZA51AS1	asafetida	digestive aid				310.545(a)(8)(ii)	
Y62M9GTW4A	asclepias tuberosa	menstrual/diuretic	botanical/vegetable herb	II	II	310.545(a)(24)(i)	
PQ6CK8PD0R	ascorbic acid	corn/callus remover		II	IIIE		[55 FR 33261]
PQ6CK8PD0R	ascorbic acid	wart remover		III	IIIIE		[55 FR 33254]
PQ6CK8PD0R	ascorbic acid	weight control			II	310.545(a)(20)	
Z1EJP3037Z	asparagus	menstrual/diuretic				310.545(a)(24)(i)	
Q6Z8UK5R3G	aspergillus oryza enzymes (except lactase enzyme derived from aspe	digestive aid				310.545(a)(8)(ii)	
R16CO5Y76E	aspirin	external analgesic	analgesic & anesthetic	III	III	310.545(a)(10)(i)	
R16CO5Y76E	aspirin	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
R16CO5Y76E	aspirin	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
R16CO5Y76E	aspirin	internal analgesic	cardiovascular	I	I	343.12(a)	
R16CO5Y76E	aspirin	internal analgesic	rheumatologic	I	I	343.13(a)	
R16CO5Y76E	aspirin	menstrual/diuretic	analgesic		I		
R16CO5Y76E	aspirin	nighttime sleep aid		II	IIIE		[54 FR 6826]
R16CO5Y76E	aspirin	oral health care	anesthetic/analgesic	I	IIIIE		
R16CO5Y76E	aspirin	overindulgence in alcohol	hangover reliever		I		
R16CO5Y76E	aspirin (buffered)	internal analgesic	cardiovascular	I	I	343.12(b)	
R16CO5Y76E	aspirin (buffered)	internal analgesic	rheumatologic	I	I	343.13(b)	
R16CO5Y76E	aspirin, aluminum	internal analgesic		III	III	310.545(a)(23)(i)	
R16CO5Y76E	aspirin, calcium	internal analgesic			I		
R16CO5Y76E	aspirin, calcium	internal analgesic			I		
R16CO5Y76E	aspirin, calcium	menstrual/diuretic			I		

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
WQZ3G9PF0H	atropa belladonna	cough/cold	anticholinergic		II	310.53	
7C0697DR9I	atropine	anorectal	anticholinergic	II(e,i)	II(e,i)	310.545(a)(26)(i)	
03J5ZE7KA5	atropine sulfate	antidiarrheal		III	III	310.545(a)(3)(i)	
03J5ZE7KA5	atropine sulfate	cough/cold	anticholinergic		III	310.53	
U6V729APAM	attapulgite, activated	antidiarrheal	w/ sales less than \$25,000	III	I	310.545(3)(ii)	
G63QQF2NOX	avobenzone	sunscreen				352.10(a)	
	bacillus acidophilus	digestive aid				310.545(a)(8)(ii)	
58H6RWO52I	bacitracin	first aid antibiotic	ointment		I	333.110(a)	
89Y4M234ES	bacitracin zinc	first aid antibiotic	ointment		I	333.110(b)	
	barosma	menstrual/diuretic				310.545(a)(24)(i)	
5P5C03819W	basic fuchsin	antifungal		III	III	310.545(a)(22)(ii)	
	beachwood creosote	cough/cold	expectorant		III	310.545(a)(6)(iii)	
8WB9PV3YW5	bean	digestive aid				310.545(a)(8)(ii)	
3M5V3D1X36	bearberry	weight control		II		310.545(a)(20)	
3M5V3D1X36	bearberry (extract of uva ursi)	menstrual/diuretic				310.545(a)(24)(i)	
3M5V3D1X36	bearberry fluidextract (extract of bearberry)	menstrual/diuretic				310.545(a)(24)(i)	
2ZA36H0S2V	beeswax	skin protectant	insect bites/stings w/ sales less than \$25,000			310.545(a)(18)(v)(B)	
2ZA36H0S2V	beeswax	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000			310.545(a)(18)(vi)(B)	
2ZA36H0S2V	beeswax	skin protectant	w/ sales less than \$25,000			310.545(a)(18)(i)(B)	
WQZ3G9PF0H	belladonna alkaloids	corn/callus remover		II	IISE		[55 FR 33261]
WQZ3G9PF0H	belladonna alkaloids	cough/cold	anticholinergic		IIIIE	310.53	
WQZ3G9PF0H	belladonna alkaloids	cough/cold	bronchodilator	II	II	310.545(a)(6)(iv)	
WQZ3G9PF0H	belladonna alkaloids	digestive aid				310.545(a)(8)(ii)	
WQZ3G9PF0H	belladonna extract	anorectal	anticholinergic	II(e,i)	II(e,i)	310.545(a)(26)(i)	
6GZW20TIOI	belladonna leaves, powdered exrtact	digestive aid				310.545(a)(8)(ii)	
PWZ1720CBH	bemotrizinol	sunscreen		NA			
F5UM2KM3W7	benzalkonium chloride	antimicrobial			I		
F5UM2KM3W7	benzalkonium chloride	antimicrobial			II		
F5UM2KM3W7	benzalkonium chloride	antimicrobial			IIISE		
F5UM2KM3W7	benzalkonium chloride	antimicrobial			IIISE		
F5UM2KM3W7	benzalkonium chloride	antimicrobial			IIISE		
F5UM2KM3W7	benzalkonium chloride	antimicrobial			IIISE		
F5UM2KM3W7	benzalkonium chloride	antimicrobial			IIISE		
F5UM2KM3W7	benzalkonium chloride	antimicrobial			IIISE		
F5UM2KM3W7	benzalkonium chloride	antimicrobial			IIISE		
F5UM2KM3W7	benzalkonium chloride	dandruff		III	III	310.545(a)(7)	
F5UM2KM3W7	benzalkonium chloride	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
F5UM2KM3W7	benzalkonium chloride	skin protectant	astringent	II		310.545(a)(18)(ii)	
F5UM2KM3W7	benzalkonium chloride	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
PH41D05744	benzethonium chloride	antifungal				310.545(a)(22)(ii)	
PH41D05744	benzethonium chloride	antimicrobial		I			
PH41D05744	benzethonium chloride	antimicrobial		IIIIE			

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
PH41D05744	benzethonium chloride	antimicrobial			IIISE		
PH41D05744	benzethonium chloride	antimicrobial			IIISE		
PH41D05744	benzethonium chloride	antimicrobial			IIISE		
PH41D05744	benzethonium chloride	antimicrobial			IIISE		
PH41D05744	benzethonium chloride	antimicrobial			IIISE		
PH41D05744	benzethonium chloride	dandruff		III	III	310.545(a)(7)	
PH41D05744	benzethonium chloride	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
PH41D05744	benzethonium chloride	skin protectant	astringent	II		310.545(a)(18)(ii)	
PH41D05744	benzethonium chloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
U3RSY48JW10	benzocaine	external analgesic			IIIIE	IISE (0.5-1.25%)	
U3RSY48JW11	benzocaine	oral health care	anesthetic/analgesic	I	I		
U3RSY48JW12	benzocaine	otic			IISE		[51 FR 28660]
U3RSY48JW13	benzocaine	pediculicide		II	II	310.545(a)(25)(i)	
U3RSY48JW14	benzocaine	relief of oral discomfort			I		
U3RSY48JW15	benzocaine	relief of oral discomfort			IIIIE		
U3RSY48JW16	benzocaine	skin protectant	astringent	II		310.545(a)(18)(ii)	
U3RSY48JW17	benzocaine	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
U3RSY48JW18	benzocaine	wart remover		II	IISE		[55 FR 33254]
U3RSY48JW19	benzocaine	weight control			IISE		
U3RSY48JW5	benzocaine	acne		II	II	310.545(a)(1)	
U3RSY48JW5	benzocaine	external analgesic	male genital desensitizer	I	I	348.10(a)(1)	
U3RSY48JW6	benzocaine	anorectal	local anesthetic	I(e),III(i)	I(e),III(i)	346.10(a)	
U3RSY48JW7	benzocaine	dandruff		II	IIE		[56 FR 63567]
U3RSY48JW9	benzocaine (0.5 - 1.25%)	external analgesic	poison ivy/oak/sumac	I	I	310.545(a)(10)(vii)	
8SKN0B0MIM	benzoic acid	acne		II	II	310.545(a)(1)	
8SKN0B0MIM	benzoic acid	antifungal		III	III	310.545(a)(22)(ii)	
8SKN0B0MIM	benzoic acid	oral health care			IIIIE		
8SKN0B0MIM	benzoic acid	skin protectant	astringent	II		310.545(a)(18)(ii)	
L7J6A1NE81	benzoin preparations (compound tincture of benzoin, tincture of benzoin tincture, compound	cough/cold	expectorant		III	310.545(a)(6)(iii)	
L7J6A1NE81	benzoin tincture, compound	relief of oral discomfort			I		
5P4DH6ENR	benzonatate	cough/cold	antitussive		I		
GRE0P19C3Z	benzoxiquine	antifungal		III	III	310.545(a)(22)(ii)	
W9WZN9A0GM	benzoyl peroxide	acne		I	I->IIIS	333.310(a)	75 FR 9767
LKG8494WBH	benzyl alcohol	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(b)	
LKG8494WBH	benzyl alcohol	external analgesic	analgesic & anesthetic	I	I	Pending	
LKG8494WBH	benzyl alcohol	external analgesic	male genital desensitizer			310.545(a)(10)(iii)	
LKG8494WBH	benzyl alcohol	oral health care	anesthetic/analgesic	I	I		
LKG8494WBH	benzyl alcohol	pediculicide		II	II	310.545(a)(25)(i)	
LKG8494WBH	benzyl alcohol	relief of oral discomfort			I		
LKG8494WBH	benzyl alcohol	relief of oral discomfort			IIIIE		
LKG8494WBH	benzyl alcohol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
N863NB338G	benzyl benzonate	pediculicide		II	II	310.545(a)(25)(i)	
JK8U8K4D6K	betaine hydrochloride	digestive aid				310.545(a)(8)(ii)	
	bicarbonate	antacid				331.11(b)	
	bile salts/acids	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
6SO6U10H04	biotin	weight control			II	310.545(a)(20)	
10X0709Y6I	bisacodyl	laxative			I		
JB5Y63JDHJ	bismuth aluminate	antacid			I	331.11(c)(1)	
M41L2IN55T	bismuth carbonate	antacid			I	331.11(c)(2)	
A614E79QF1	bismuth oxide	anorectal	protectant	III(e,i)	III(e,i)	310.545(a)(26)(viii)	
	bismuth sodium tartrate	digestive aid		II	II	310.545(a)(8)(i)	
	bismuth sodium tartrate	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
M41L2IN55T	bismuth subcarbonate	anorectal	protectant	III(e,i)	III(e,i)	310.545(a)(26)(viii)	
M41L2IN55T	bismuth subcarbonate	antacid			I	331.11(c)(3)	
M41L2IN55T	bismuth subcarbonate	digestive aid				310.545(a)(8)(ii)	
YIW503MI7V	bismuth subgallate	anorectal	protectant	III(e,i)	III(e,i)	310.545(a)(26)(viii)	
YIW503MI7V	bismuth subgallate	antacid			I	331.11(c)(4)	
YIW503MI7V	bismuth subgallate	deodorants for internal use		III	I	357.810(a)	
YIW503MI7V	bismuth subgallate	digestive aid				310.545(a)(8)(ii)	
H19J064BA5	bismuth subnitrate	skin protectant		II	IIS		
YIW503MI7V	bismuth subnitrate	anorectal	protectant	II(e,i)	II(e,i)	310.545(a)(26)(viii)	
YIW503MI7V	bismuth subnitrate	antacid			I	331.11(c)(5)	
YIW503MI7V	bismuth subnitrate	antidiarrheal	w/ sales less than \$25,000	III	III	310.545(a)(3)(ii)	
YIW503MI7V	bismuth subnitrate	skin protectant	fever blister/cold sore		II	310.545(a)(18)(iv)	
YIW503MI7V	bismuth subnitrate	skin protectant	insect bites/stings w/ sales less than \$2	II	II	310.545(a)(18)(v)(B)	
YIW503MI7V	bismuth subnitrate	skin protectant	poison ivy/oak/sumac	II	II	310.545(a)(18)(vi)(A)	
YIW503MI7V	bismuth subnitrate	skin protectant	poison ivy/oak/sumac w/ sales less than	II	II	310.545(a)(18)(vi)(B)	
YIW503MI7V	bismuth subnitrate	skin protectant	w/ sales less than \$25,000	II	II	310.545(a)(18)(i)(B)	
62TEY51RR1	bismuth subsalicylate	antidiarrheal		III	IIIIE	335.10(a)	
62TEY51RR2	bismuth subsalicylate	antiemetic			III		
62TEY51RR3	bismuth subsalicylate	antimicrobial			IISE		
62TEY51RR4	bismuth subsalicylate	oral health care			IISE		
62TEY51RR5	bismuth subsalicylate	overindulgence in alcohol	overindulgence		I		
8NT850T0YS	bisoctrizole	sunscreen			NA		
AMT77LS62O	bithionol	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
AMT77LS62O	bithionol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
86R5J6D01D	black radish powder	digestive aid				310.545(a)(8)(ii)	
6L5ZL09795	blessed thistle (cnicus benedictus)	digestive aid				310.545(a)(8)(ii)	
6L5ZL09795	blessed thistle (cnicus benedictus)	menstrual/diuretic				310.545(a)(24)(i)	
	bone marrow, red	weight control			II	310.545(a)(20)	
R57ZHV85D10	boric acid	skin protectant	fever blister/cold sore		II	310.545(a)(18)(iv)	
R57ZHV85D11	boric acid	skin protectant	insect bites/stings w/ sales less than \$2	II	II	310.545(a)(18)(v)(B)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
R57ZHV85D12	boric acid	skin protectant	poison ivy/oak/sumac	II	II	310.545(a)(18)(vi)(A)	
R57ZHV85D13	boric acid	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000	II	II	310.545(a)(18)(vi)(B)	
R57ZHV85D14	boric acid	skin protectant	w/ sales less than \$25,000	II	II	310.545(a)(18)(i)(B)	
R57ZHV85D4	boric acid	acne		II	II	310.545(a)(1)	
R57ZHV85D5	boric acid	anorectal	antiseptic	II(e,i)	II(e,i)	310.545(a)(26)(ii)	
R57ZHV85D6	boric acid	antifungal		III		310.545(a)(22)(ii)	
R57ZHV85D7	boric acid	dandruff		II	II	310.545(a)(7)	
R57ZHV85D8	boric acid	ophthalmic	anti-infective	III	II	310.545(a)(21)(ii)	
R57ZHV85D9	boric acid	skin protectant	astringent	II	II	310.545(a)(18)(ii)	
LU86E5P72A	bornelone (5-(3,3-dimethyl-2-norbornyliden)3-pentene-2-one)	sunscreen		III	IIIIE		58 FR 28281
	bornyl acetate (topical)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
	boroglycerin	anorectal	antiseptic	II(e,i)	II(e,i)	310.545(a)(26)(ii)	
	boroglycerin	oral health care			IISE		
	bran	laxative			I		
IXA7C9ZN03	brompheniramine maleate	cough/cold	antihistamine	I	I	341.12(a)	
KOS935A04V	buchu	weight control			II	310.545(a)(20)	
KOS935A04V	buchu powdered extract (extract of buchu)	menstrual/diuretic		II	II	310.545(a)(24)(i)	
KOS935A04V	buchu, potassium extract	weight control			II	310.545(a)(20)	
2C5Q57D7Z4	buckthorn	digestive aid				310.545(a)(8)(ii)	
PAU39W3CVB	butacaine sulfate	relief of oral discomfort			I		
PAU39W3CVB	butacaine sulfate	relief of oral discomfort			IISE		
	butamben picrate	external analgesic		I	I		
3G6A5W338E	caffeine	cough/cold	miscellaneous			IIIIE	
3G6A5W338E	caffeine	internal analgesic		III	IIIIE		
3G6A5W338E	caffeine	menstrual/diuretic	analgesic	III			
3G6A5W338E	caffeine	menstrual/diuretic	diuretic	I	I		
3G6A5W338E	caffeine	nighttime sleep aid	stimulant		I		
3G6A5W338E	caffeine	overindulgence in alcohol hangover reliever			I		
3G6A5W338E	caffeine	stimulant			I	340.10	
3G6A5W338E	caffeine	weight control			II	310.545(a)(20)	
U26EO4675Q	caffeine citrate	weight control			II	310.545(a)(20)	
	calamine	anorectal	astringent	I(e,i)	I(e,i)	346.18(a)	
	calamine	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
	calamine	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
	calamine	skin protectant		I	I	347.10(c)	
	calamine (in combination only)	anorectal	protectant	I(e,i)	I(e,i)	346.14(b)(1)	
	calcium	weight control			II	310.545(a)(20)	
SY7Q814VUP	calcium (mono or dibasic salt)	antacid				331.11(i)(2)	
Y882YXF34X	calcium acetate	skin protectant	astringent	II		310.545(a)(18)(ii)	
H0G9379FGK	calcium carbonate	antacid			I	331.11(d)	
H0G9379FGK	calcium carbonate	digestive aid	antacid	III	I	310.545(a)(8)(i)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
H0G9379FGK	calcium carbonate	weight control			II	310.545(a)(20)	
H0G9379FGK	calcium carbonate precipitated	antidiarrheal		III	III	310.545(a)(3)(i)	
	calcium caseinate	weight control			II	310.545(a)(20)	
SQE6VB453K	calcium gluconate	digestive aid				310.545(a)(8)(ii)	
PF5DZW74VN	calcium hydroxide	antidiarrheal	w/ sales less than \$25,000	III	III	310.545(a)(3)(ii)	
2URQ2N32W3	calcium lactate	menstrual/diuretic				310.545(a)(24)(i)	
2URQ2N32W3	calcium lactate	weight control			II	310.545(a)(20)	
568ET80C3D	calcium pantothenate	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
568ET80C3D	calcium pantothenate	menstrual/diuretic				310.545(a)(24)(i)	
568ET80C3D	calcium pantothenate	wart remover		III	III		[55 FR 33254]
568ET80C3D	calcium pantothenate	weight control			II	310.545(a)(20)	
H0G9379FGK	calcium phosphate	antacid			I	331.11(d)	
	calcium polycarbophil	antidiarrheal	w/ sales less than \$25,000	NC	I	310.545(a)(3)(ii)	
	calcium polycarbophil	laxative	bulk laxative		I		
	calcium polysulfide	acne		II	II	310.545(a)(1)	
	calcium salicylate	internal analgesic				310.545(a)(23)(i)	
	calcium sucrose phosphate	anticaries		II	NC	310.545(a)(2)(ii)	
210100728E	calcium thiosulfate	acne		II	II	310.545(a)(1)	
77YW1RTU8V	calcium undecylenate	antifungal		I	I	333.210(f)	
77YW1RTU8V	calcium undecylenate	antimicrobial			II		
77YW1RTU8V	calcium undecylenate	dandruff				310.545(a)(7)	
J2D46N657D	calomel	laxative	stimulant laxative		II	310.545(a)(12)(iv)(A)	
J2D46N657D	calomel (mercurous chloride)	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
5TJD82A1ET	camphor	acne		II	II	310.545(a)(1)	
5TJD82A1ET	camphor	anorectal	analgesic, anesthetic, antipruritic		I(e)	346.16(a)	
5TJD82A1ET	camphor	anorectal	counterirritant	II(e,i)	II(e,i)	310.545(a)(26)(iv)	
5TJD82A1ET	camphor	antifungal		II	II	310.545(a)(22)(ii)	
5TJD82A1ET	camphor	cough/cold	antitussive	III	III	341.14(b)(1)	steam inhalation
5TJD82A1ET	camphor	cough/cold	antitussive	III	I	341.14(b)(1)	topical
5TJD82A1ET	camphor	cough/cold	expectorant		III	310.545(a)(6)(iii)	topical/inhalant
5TJD82A1ET	camphor	cough/cold	nasal decongestant	III	III		[59 FR 43408]
5TJD82A1ET	camphor	external analgesic		I	I		
5TJD82A1ET	camphor	external analgesic		I	II		
5TJD82A1ET	camphor	oral health care	anesthetic/analgesic	II	II		
5TJD82A1ET	camphor	oral health care	non antimicrobial			310.545(a)(14)	
5TJD82A1ET	camphor	relief of oral discomfort			II		
5TJD82A1ET	camphor	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
5TJD82A1ET	camphor	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
5TJD82A1ET	camphor	sunscreen		inactive			43 FR 38208
5TJD82A1ET	camphor	wart remover		II	II		[55 FR 33254]
5TJD82A1ET	camphor (exceeding 3 percent)	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
5TJD82A1ET	camphor (lozenge)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
5TJD82A1ET	camphor gum	skin protectant	astringent	II		310.545(a)(18)(ii)	
	camphorated metacresol	antifungal		III	III	310.545(a)(22)(iv)	
	camphorated metacresol	external analgesic	analgesic & anesthetic	IIIE	I	Pending	
	camphorated metacresol	external analgesic	male genital desensitizer			310.545(a)(10)(iii)	
	candidicin	antifungal		II	II	310.545(a)(22)(ii)	
S07O44R1ZM	capsaicin	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
S07O44R1ZM	capsicum	digestive aid				310.545(a)(8)(ii)	
S07O44R1ZM	capsicum	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
S07O44R1ZM	capsicum	relief of oral discomfort				IIIIE	
S07O44R1ZM	capsicum	relief of oral discomfort				IIIE	
S07O44R1ZM	capsicum oleoresin	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
S07O44R1ZM	capsicum oleoresin	menstrual/diuretic				310.545(a)(24)(i)	
S07O44R1ZM	capsicum, fluid extract of carbon	digestive aid				310.545(a)(8)(ii)	
	captan	dandruff		III	III	310.545(a)(7)	
09TQU5PG95	caramiphen edisylate	cough/cold	antitussive	III	IIIIE		[52 FR 30054]
31PZ2VAU81	carbamide peroxide	oral health care				III	
31PZ2VAU81	carbamide peroxide	oral health care				IIIIE	
31PZ2VAU81	carbamide peroxide (in anhydrous glycerin)	oral health care	wound cleansing	I	I		
31PZ2VAU81	carbamide peroxide 6.5% (in anhydrous glycerin)	otic			I	344.10	
N667F17JP1	carbaspirin calcium	internal analgesic		I	I		
N667F17JP1	carbaspirin calcium	menstrual/diuretic	analgesic	I			
4SH0MFJ5HJ	carbetapentane citrate	cough/cold	antitussive	III	IIIIE		[52 FR 30054]
2P3VWU3H10	carbon	digestive aid					
142M471B3J	carbon dioxide, released	laxative			I		
K679OBS311	carboxymethylcellulose sodium	antidiarrheal				310.545(a)(3)(i)	
K679OBS311	carboxymethylcellulose sodium	laxative			I		
K679OBS311	carboxymethylcellulose sodium	ophthalmic	demulcents	I	I	349.12(a)(1)	
K679OBS311	carboxymethylcellulose sodium	weight control			III	310.545(a)(20)	
5C69YCD2YJ	carrageenan	weight control			III	310.545(a)(20)	
5C69YCD2YJ	carrageenan (degraded)	laxative	bulk laxative	II		310.545(a)(12)(i)	
5C69YCD2YJ	carrageenan (native)	laxative	bulk laxative	III		310.545(a)(12)(i)	
	casanthranol	laxative	stimulant laxative	I		310.545(a)(12)(iv)(C)	
	cascara fluidextract aromatic	laxative	stimulant laxative	I		310.545(a)(12)(iv)(C)	
	cascara fluidextract, aromatic (extract of cascara)	menstrual/diuretic				310.545(a)(24)(i)	
4VBP01X99F	cascara sagrada bark	laxative	stimulant laxative	I		310.545(a)(12)(iv)(C)	
	cascara sagrada extract	digestive aid				310.545(a)(8)(ii)	
	cascara sagrada extract	laxative	stimulant laxative	I		310.545(a)(12)(iv)(C)	
	cascara sagrada fluidextract	laxative	stimulant laxative	I		310.545(a)(12)(iv)(C)	
D5340Y2I9G	castor oil	laxative	stimulant laxative	I			
D5340Y2I9G	castor oil	wart remover		II	IIIE		[55 FR 33254]

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
483O0360NZ	catechu, tinctures	digestive aid				310.545(a)(8)(ii)	
7Y51EV0DZW	catnip	digestive aid				310.545(a)(8)(ii)	
BJ169U4NLG	cedar leaf oil (topical)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
	cellulase	digestive aid		II/III	III	310.545(a)(8)(i)	
SMD1X3XO9M	cellulose, microporous	skin protectant	diaper rash		IIISE		
85474O1N9D	cetalkonium chloride	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
85474O1N9D	cetalkonium chloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
936JST6JCN	cetyl alcohol	skin protectant	insect bites/stings w/ sales less than \$25,000			310.545(a)(18)(v)(B)	
936JST6JCN	cetyl alcohol	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000			310.545(a)(18)(vi)(B)	
936JST6JCN	cetyl alcohol	skin protectant	w/ sales less than \$25,000			310.545(a)(18)(i)(B)	
D9OM4SK49P	cetylpyridinium chloride	oral health care			IIISE		
O2T154T6OG	chamomile flowers	digestive aid				310.545(a)(8)(ii)	
2P3VWU3H10	charcoal (activated)	antidiarrheal	w/ sales less than \$25,000	III	III	310.545(a)(3)(ii)	
2P3VWU3H10	charcoal, activated		acute toxic ingestion		I		
2P3VWU3H10	Charcoal, activated	antacid			IIIIE		
2P3VWU3H10	charcoal, activated		deodorants for internal use	III	III		[55 FR 19864]
2P3VWU3H10	charcoal, activated		overindulgence in a hangover minimizer		IIIIE		[48 FR 32873]
2P3VWU3H10	charcoal, activated		poison treatment		I		
2P3VWU3H10	charcoal, wood/activated	digestive aid		III	III	310.545(a)(8)(iii)	
69QQ58998Y	chlophedianol hydrochloride	cough/cold	antitussive		I	341.14(a)(1)	oral
418M5916WG	chloral hydrate	external analgesic	analgesic & anesthetic	II	II	310.545(a)(10)(i)	
418M5916WG	chloral hydrate	external analgesic	counter irritant	I	I	310.545(a)(10)(ii)	
418M5916WG	chloral hydrate	external analgesic	fever blister/cold sore	II	II	310.545(a)(10)(v)	
418M5916WG	chloral hydrate	external analgesic	poison ivy/oak/sumac	II	II	310.545(a)(10)(vii)	
418M5916WG	chloral hydrate	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
NPB7A7874U	chlorcyclizine hydrochloride	cough/cold	antihistamine		I	341.12(b)	
BPF36H1G6S	chlorhydroxyquinoline (cloxyquin)	acne		II	II	310.545(a)(1)	
HM4YQM8WRC	chlorobutanol		corn/callus remover	II	IIISE		[55 FR 33261]
HM4YQM8WRC	chlorobutanol	external analgesic	analgesic & anesthetic	III	III	310.545(a)(10)(i)	
HM4YQM8WRC	chlorobutanol	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
HM4YQM8WRC	chlorobutanol	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
7V31YC746X	chloroform	cough/cold	expectorant		II	310.545(a)(6)(iii)	
7V31YC746X	chloroform	digestive aid				310.545(a)(8)(ii)	
CIW5S16655	chlorophenothane (dichlorodiphenyl trichloroethane)	pediculicide				310.545(a)(25)(i)	
	chlorophyllin		relief of oral discomfort		IIISE		
	chlorophyllin copper complex		deodorants for internal use	III	I	357.810(b)	
	chlorophyllin copper complex		oral health care		IIIIE		
LJ25TI0CVT	chlorothymol	antifungal		III	III	310.545(a)(22)(ii)	
LJ25TI0CVT	chloroxlyneol	antimicrobial			IIIIE		
LJ25TI0CVT	chloroxlyneol	antimicrobial			IIIIE		
LJ25TI0CVT	chloroxlyneol	antimicrobial			IIISE		

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
LJ25T10CVT	chloroxyneol	antimicrobial			IIISE		
LJ25T10CVT	chloroxyneol	antimicrobial			IIISE		
LJ25T10CVT	chloroxyneol	antimicrobial			IIISE		
LJ25T10CVT	chloroxyneol	antimicrobial			IIISE		
LJ25T10CVT	chloroxyneol	antimicrobial			IIISE		
LJ25T10CVT	chloroxyneol	antimicrobial			IIISE		
LJ25T10CVT	chloroxyneol	antimicrobial			IIISE		
LJ25T10CVT	chloroxylenol	acne		II	II	310.545(a)(1)	
LJ25T10CVT	chloroxylenol	antifungal		III	III	310.545(a)(22)(iv)	
LJ25T10CVT	chloroxylenol	dandruff		III	III	310.545(a)(7)	
V1Q0O9OJ9Z	chlorpheniramine maleate	cough/cold	antihistamine	I	I	341.12(c)	
V1Q0O9OJ9Z	chlorpheniramine maleate	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
V1Q0O9OJ9Z	chlorpheniramine maleate	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
	chlorprophenpyridamine maleate	menstrual/diuretic				310.545(a)(24)(i)	
O1GX33ON8R	chlortetracycline hydrochloride	first aid antibiotic	ointment	I		333.110(c)	
1C6V77QF41	cholecalciferol	skin protectant	diaper rash		IIISE		
1C6V77QF41	cholecalciferol	weight control		II		310.545(a)(20)	
1C6V77QF41	cholecalciferol (vitamin D)	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	
N91BDP6H0X	choline	weight control		II		310.545(a)(20)	
N91BDP6H0X	choline salicylate	internal analgesic		I	I		
N91BDP6H0X	choline salicylate	menstrual/diuretic	analgesic	I			
XR12Z4HLEA	chondrus	weight control		III		310.545(a)(20)	
K73E24S6X9	cimicifuga racemosa	menstrual/diuretic	botanical/vegetable herb	II	II	310.545(a)(24)(i)	
T4B6SPQ0UF	cinnamedrine hydrochloride	menstrual/diuretic	muscle relaxant	III	IIIIE		
E5GY4I6YCZ	cinnamon oil	digestive aid				310.545(a)(8)(ii)	
5S29HWU6QB	cinnamon tincture	digestive aid				310.545(a)(8)(ii)	
5437O7N5BH	cinoxate	sunscreen		I	I	352.10(c)	
	citrate (containing active ingredients: citrate ion, as citric acid or salt)	antacid			I	331.11(e)	
2968PHW8QP	citric acid	relief of oral discomfort			IIIIE		
2968PHW8QP	citric acid	weight control		II		310.545(a)(20)	
47EQ08LE7H	citrus pectin	digestive aid				310.545(a)(8)(ii)	
7BHQ856EJ5	clioquinol	antifungal		I	I	333.210(a)	
7BHQ856EJ5	clioquinol (iodochlorhydroxyquin)	antifungal		I	I	333.210(a)	
I5ZZY3DC5G	cloflucarban	antimicrobial			IIIS		
I5ZZY3DC5G	cloflucarban	antimicrobial			IIISE		
I5ZZY3DC5G	cloflucarban	antimicrobial			IIISE		
I5ZZY3DC5G	cloflucarban	antimicrobial			IISE		
I5ZZY3DC5G	cloflucarban	antimicrobial			IISE		
I5ZZY3DC5G	cloflucarban	antimicrobial			IISE		
I5ZZY3DC5G	cloflucarban	antimicrobial			IISE		
G07GZ97H65	clotrimazole	antifungal		I		333.210(g)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
G07GZ97H65	clotrimazole	n/a			I		[67 FR 5942]
578389D6D0	clove oil	skin protectant	astringent	II		310.545(a)(18)(ii)	
BPF36H1G6S	cloxyquin (chlorhydroxyquinoline)	acne				310.545(a)(1)	
6L5ZL09795	cnicus benedictus	menstrual/diuretic		II	II		
6L5ZL09795	cnicus benedictus	weight control			II	310.545(a)(20)	
R533ES02EC	coal tar	acne		II	II	310.545(a)(1)	
R533ES02EC	coal tar	antifungal		II	II	310.545(a)(22)(ii)	
R533ES02EC	coal tar	dandruff	psoriasis	ISIII	I	358.710(c)(1)	
R533ES02EC	coal tar	dandruff	seborrheic dermatitis	ISIII	I	358.710(b)(1)	
R533ES02EC	coal tar	dandruff		ISIII	I	358.710(a)(1)	
5120YT1CRR	cocoa butter	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(2)	
5120YT1CRR	cocoa butter	skin protectant	diaper rash		III	310.545(a)(18)(iii)	
5120YT1CRR	cocoa butter	skin protectant	diaper rash		iii	310.545(a)(18)(iii)	
5120YT1CRR	cocoa butter	skin protectant	fever blister/cold sore		I		
5120YT1CRR	cocoa butter	skin protectant		I	I	347.10(d)	
	coconut oil soap, aqueous	pediculicide		II	II	310.545(a)(25)(i)	
BBL281NWFG	cod liver oil	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	
BBL281NWFG	cod liver oil	cough/cold	antitussive	III	IIIIE		[52 FR 30054]
BBL281NWFG	cod liver oil	skin protectant	diaper rash				
BBL281NWFG	cod liver oil (in combination only)	anorectal	protectant	I(e,i)	I(e,i)	346.14(b)(2)	
Q830PW7520	codeine	cough/cold	antitussive	I	I	341.14(a)(2)(i)	oral
Q830PW7520	codeine	internal analgesic		II	II	310.545(a)(23)(i)	
Q830PW7520	codeine	menstrual/diuretic	analgesic	II		310.545(a)(24)(i)	
GSL05Y1MN6	codeine phosphate	cough/cold	antitussive	I	I	341.14(a)(2)(ii)	oral
GSL05Y1MN6	codeine phosphate	internal analgesic				310.545(a)(23)(i)	
11QV9BS0CB	codeine sulfate	cough/cold	antitussive	I	I	341.14(a)(2)(iii)	oral
11QV9BS0CB	codeine sulfate	internal analgesic				310.545(a)(23)(i)	
J9BTD5377V	collinsonia (extract stone root)	menstrual/diuretic				310.545(a)(24)(i)	
IOS9HV04K7	collinsonia extract	anorectal	other	II(e,i)	II(e,i)	310.545(a)(26)(vii)	
8PI54V663Y	colloidal oatmeal	dandruff		II	II	310.545(a)(7)	
8PI54V663Y	colloidal oatmeal	skin protectant	astringent	II		310.545(a)(18)(ii)	
8PI54V663Y	colloidal oatmeal	skin protectant	diaper rash		III		
8PI54V663Y	colloidal oatmeal	skin protectant			I	347.10(f)	
23H32AOH17	colocynth	laxative	stimulant laxative		II	310.545(a)(12)(iv)(A)	
789U1901C5	copper	weight control			II	310.545(a)(20)	
789U1901C5	copper gluconate	weight control			II	310.545(a)(20)	
789U1901C5	copper oleate	pediculicide		II	II	310.545(a)(25)(i)	
789U1901C5	copper undecylenate	antifungal		I	I	333.210(f)	
8470G57WFM	corn oil	weight control			II	310.545(a)(20)	
	corn oil, aqueous emulsion	cholecystokinetic			I	357.210(a)	
7D3VB244UX	corn silk	menstrual/diuretic		II	II	310.545(a)(24)(i)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
	corn silk, potassium extract	weight control			II	310.545(a)(20)	
O8232NY3SJ	corn starch	skin protectant			I	347.10(q)	
9G5L16BK6N	corn syrup	weight control			II	310.545(a)(20)	
8K1MK5E1FY	couch grass	menstrual/diuretic				310.545(a)(24)(i)	
	creosote	relief of oral discomfort			IIIIE		
	creosote	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
	creosote, beechwood	cough/cold	antitussive	III	IIIIE		[52 FR 30054]
	creosote, beechwood	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
	creosote, beechwood	relief of oral discomfort			IIISE		
	creosote, beechwood (oral)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
	creosote, beechwood (topical)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
1MXY2UM8NV	cresol	oral health care	anesthetic/analgesic	II	IISE		
1MXY2UM8NV	cresol	oral health care	non-antimicrobial			310.545(a)(14)	
1MXY2UM8NV	cresol	relief of oral discomfort			IIISE		
1MXY2UM8NV	cresol	relief of oral discomfort			IIISE		
1MXY2UM8NV	cresol	skin protectant	astringent	II		310.545(a)(18)(ii)	
1MXY2UM8NV	cresol, saponated	dandruff		II	II	310.545(a)(7)	
LRX7AJ16DT	cupric sulfate	external analgesic					
LRX7AJ16DT	cupric sulfate	skin protectant	astringent	II		310.545(a)(18)(ii)	
LRX7AJ16DT	cupric sulfate	weight control			II	310.545(a)(20)	
P6YC3EG204	cyanocobalamin (vitamin B12)	weight control			II	310.545(a)(20)	
W0O1NHP4WE	cyclizine hydrochloride	antiemetic			I	336.10(a)	
7323N7T136	cyclomethycaine sulfate	external analgesic	analgesic & anesthetic	III	III	310.545(a)(10)(i)	
7323N7T136	cyclomethycaine sulfate	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
7323N7T136	cyclomethycaine sulfate	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
ZT934N0X4W	cysteine hydrochloride	skin protectant	diaper rash			310.545(a)(18)(iii)	
48TCX9A1VT	cystine	weight control			II	310.545(a)(20)	
Z4XE6IBF3V	danthon	laxative	stimulant laxative		I	310.545(a)(12)(iv)(B)	
	datura stramonium	cough/cold	anticholinergic		II	310.53	
NH5000009I	dehydrocholic acid	digestive aid			II	310.545(a)(8)(i)	
XYS8INN1I6	dequalinium chloride	oral health care			IIISE		
BPA9UT29BS	dexbrompheniramine maleate	cough/cold	antihistamine		I	341.12(d)	
B10YD955QW	dexchlorpheniramine maleate	cough/cold	antihistamine		I	341.12(e)	
1O6C93RI7Z	dexpanthenol	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
1O6C93RI7Z	dexpanthenol	external analgesic			IIIIE		
1O6C93RI7Z	dexpanthenol	skin protectant	diaper rash		IIISE		
7SA290YK68	dextran 70	ophthalmic	demulcents		I	349.12(b)	
7355X3ROTS	dextromethorphan	cough/cold	antitussive		I	341.14(a)(3)	oral
9D2RTI9KYH	dextromethorphan hydrobromide	cough/cold	antitussive		I	341.14(a)(4)	oral
IY9XDZ35W2	dextrose	weight control			II	310.545(a)(20)	
	diastase	digestive aid				310.545(a)(8)(ii)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
	diastase malt	digestive aid				310.545(a)(8)(ii)	
Z3D4AJ1R48	dibenzothiophene	acne		II	II	310.545(a)(1)	
L6JW2TJG99	dibucaine	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(c)	
L6JW2TJG99	dibucaine	external analgesic		I	I		
L6JW2TJG99	dibucaine	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
Z97702A5DG	dibucaine hydrochloride	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(d)	
Z97702A5DG	dibucaine hydrochloride	external analgesic		I	I		
Z97702A5DG	dibucaine hydrochloride	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
O7TSZ97GEP	dicalcium phosphate dihydrate	anticaries		II	NC	310.545(a)(2)(ii)	
O7TSZ97GEP	dicalcium phosphate dihydrate [see calcium phosphate, dibasic]	gingivitis/plaque			IIIIE		
	dichlorodiphenyl trichloroethane (DDT)	pediculicide		II	II		
T1J0JOU64O	dichlorophen	antifungal		III	III	310.545(a)(22)(ii)	
2UTZ0QC864	diethylhexyl butamido triazone	sunscreen		NA			
PGQ9BY2MDE	digalloyl trioleate	sunscreen		I	I	310.545(a)(29)	
D0250MG0W6	dihydroxyaluminum aminoacetate	antacid			I	331.11(a)(3)	
D0250MG0W6	dihydroxyaluminum aminoacetic acid	antacid				331.11(a)(3)	
84H8Z9550J	dihydroxyaluminum sodium carbonate	antacid			I	331.11(a)(5)	
84H8Z9550J	dihydroxyaluminum sodium carbonate	digestive aid	antacid	III	I	310.545(a)(8)(i)	
JB937PER5C	dimenhydrinate	antiemetic			I	336.10(b)	
92RU3N3Y1O	dimethicone	skin protectant	diaper rash		I		
92RU3N3Y1O	dimethicone	skin protectant	fever blister/cold sore		I		
92RU3N3Y1O	dimethicone	skin protectant		I	I	347.10(g)	
SMP2689462	dimethisoquin hydrochloride	external analgesic		I	I		
F05Q2T2JA0	diocetyl sodium sulfosuccinate	pediculicide		II	II		
	diolamine methoxycinnamate (diethanolamine methoxycinnamate)	sunscreen		I	I	310.545(a)(29)	
B762XZ551X	dioxybenzone	sunscreen		I	I	352.10(e)	
2456GO94TR	diperodon	anorectal	anesthetic			310.545(a)(26)(vi)	
5YZ5R8I73Y	diperodon hydrochloride	corn/callus remover		II	IISE		[55 FR 33261]
5YZ5R8I73Y	diperodon hydrochloride	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
5YZ5R8I73Y	diperodon hydrochloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
8GTS82S83M	diphenhydramine citrate	cough/cold	antihistamine			341.12(f)	
8GTS82S83M	diphenhydramine citrate	cough/cold	antitussive			341.14(a)(5)	oral
8GTS82S83M	diphenhydramine citrate	nighttime sleep aid				338.10(b)	
TC2D6JAD40	diphenhydramine hydrochloride	antiemetic			IIIIE	336.10(c)	
TC2D6JAD41	diphenhydramine hydrochloride	cough/cold	antihistamine	I	I	341.12(g)	
TC2D6JAD42	diphenhydramine hydrochloride	cough/cold	antitussive	III	IIIIE	341.14(a)(6)	oral
TC2D6JAD43	diphenhydramine hydrochloride	external analgesic		I	I		
TC2D6JAD44	diphenhydramine hydrochloride	nighttime sleep aid	antihistamine	III	IIISE	338.10(a)	
TC2D6JAD45	diphenhydramine hydrochloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
	dipropylene glycol salicylate	sunscreen		III	IIISE		58 FR 28281
	disodium hydrogen phosphate	anticaries		II	NC	310.545(a)(2)(ii)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
6K7YS503HC	docusate calcium sulfosuccinate	laxative	stool softener				
CIK9F54ZHR	docusate potassium sulfosuccinate	laxative	stool softener				
F05Q2T2JA0	docusate sodium	pediculicide				310.545(a)(25)(i)	
F05Q2T2JA0	docusate sodium	weight control		II		310.545(a)(20)	
F05Q2T2JA0	docusate sodium sulfosuccinate	laxative	stool softener				
	dodecaethylene glycol monolaurate (polyethylene glycol 600 monolaurate)	vaginal contraceptive			III E	310.545(a)(28)(i)	
8K1MK5E1FY	dog grass	digestive aid				310.545(a)(8)(ii)	
8K1MK5E1FY	dog grass extract	menstrual/diuretic		II	II	310.545(a)(24)(i)	
R4CY19YS7C	domiphen bromide	oral health care				III SE	
V9BI9B5YI2	doxylamine succinate	cough/cold	antihistamine		I	341.12(h)	
V9BI9B5YI2	doxylamine succinate	nighttime sleep aid	antihistamine	III	II SE		[5 FR 6828]
5X93W9OFZL	drometrizole trisiloxane	sunscreen		NA			
	duodenal substance	digestive aid		II	II	310.545(a)(8)(i)	
ZEC193879Q	dyclonine hydrochloride	anorectal	local anesthetic		I	346.10(e)	
ZEC193879Q	dyclonine hydrochloride	external analgesic		I	I		
ZEC193879Q	dyclonine hydrochloride	oral health care	anesthetic/analgesic	I	I		
M94R1PM439	ecamsule	sunscreen		NA			
7FLD91C86K	edetate disodium	relief of oral discomfort				II SE	
	elaterin resin	laxative	stimulant laxative		II	310.545(a)(12)(iv)(A)	
E55SMD6DA8	elecampane	digestive aid				310.545(a)(8)(ii)	
91QY4PXU8Q	elm bark	cough/cold	antitussive	III	III E		[52 FR 30054]
91QY4PXU8Q	elm bark	oral health care	demulcents	I	I		
9YQ9DI1W42	ensulizole (phenylbenzimidazole sulfonic acid)	sunscreen		I	I	352.10(n)	
8I3XWY40L9	enzacamene (4-methylbenzylidene camphor)	sunscreen					
GN83C131XS	ephedrine	cough/cold	bronchodilator	I	I	341.16(a)	
GN83C131XS	ephedrine (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(2)	
GN83C131XS	ephedrine (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(2)	
GN83C131XS	ephedrine (oral)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
NLJ6390P1Z	ephedrine hydrochloride	cough/cold	bronchodilator	I	I	341.16(b)	
NLJ6390P1Z	ephedrine hydrochloride	external analgesic	male genital desensitizer			310.545(a)(10)(iii)	
NLJ6390P1Z	ephedrine hydrochloride	ophthalmic	vasoconstrictor	I	I	349.18(a)	
NLJ6390P1Z	ephedrine hydrochloride (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(3)	
NLJ6390P1Z	ephedrine hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(3)	
NLJ6390P1Z	ephedrine hydrochloride (oral)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
U6X61U5ZEG	ephedrine sulfate	anorectal	vasoconstrictor	I	I	346.12(a)	
U6X61U5ZEG	ephedrine sulfate	cough/cold	bronchodilator	I	I	341.16(c)	
U6X61U5ZEG	ephedrine sulfate (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(4)	
U6X61U5ZEG	ephedrine sulfate (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(4)	
U6X61U5ZEG	ephedrine sulfate (oral)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(B)	
YKH834O4BH	epinephrine	anorectal	vasoconstrictor	III (e,i)	I (e), III (i)	346.12(b)	
YKH834O4BH	epinephrine	cough/cold	bronchodilator	I	I	341.16(d)	inhalation

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
YKH834O4BH	epinephrine	cough/cold	bronchodilator	I	I	341.16(d)	rubber bulb
30Q7KI53AK	epinephrine bitartrate	cough/cold	bronchodilator	I	I	341.16(e)	inhalation
30Q7KI53AK	epinephrine bitartrate	cough/cold	bronchodilator	I	I	341.16(e)	rubber bulb
WBB047OO38	epinephrine hydrochloride	anorectal	vasoconstrictor	I(e),II(i)	I(e),II(i)	346.12(c)	
WBB047OO38	epinephrine hydrochloride	cough/cold	bronchodilator	I	I		
	epinephrine undecylenate	anorectal	vasoconstrictor	I	I	310.545(a)(26)(ix)	
VS041H42XC	ergocalciferol	weight control			II	310.545(a)(20)	
X3S33EX3KW	ergot fluid extract	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
X3S33EX3KW	ergot fluidextract	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
514B9K0L10	Escherichia coli vaccine	anorectal	other			310.545(a)(26)(vii)	
2DI9HA706A	estrone	acne		II	II	310.545(a)(1)	
0F5N573A2Y	ether	digestive aid				310.545(a)(8)(ii)	
M9JGK7U88V	ethohexadiol	dandruff		III	III	310.545(a)(7)	
54M9O25201	ethyl 4-[bis(hydroxypropyl)] aminobenzoate (roxadimate)	sunscreen		I	I	310.545(a)(29)	64 FR 27670
E1ZT886LR5	ethyl nitrate	menstrual/diuretic				310.545(a)(24)(i)	
MFM5450P3T	ethylmorphine hydrochloride	cough/cold	antitussive	III	III E		[52 FR 30054]
RV6J6604TK	eucalyptol	cough/cold	antitussive		III E		[52 FR 30055]
RV6J6604TK	eucalyptol	cough/cold	antitussive		III E		[52 FR 30055]
RV6J6604TK	eucalyptol	dandruff		III	III	310.545(a)(7)	
RV6J6604TK	eucalyptol	oral health care	anesthetic/analgesic	III	III	310.545(a)(14)	
RV6J6604TK	eucalyptol (lozenge)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
RV6J6604TK	eucalyptol (mouthwash)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
2R04ONI662	eucalyptol/eucalyptus oil	cough/cold	expectorant			310.545(a)(6)(iii)	
2R04ONI663	eucalyptus oil	cough/cold	antitussive	III	III E		[52 FR 30055]
2R04ONI664	eucalyptus oil	cough/cold	antitussive	III	III E		[52 FR 30054]
2R04ONI665	eucalyptus oil	cough/cold	antitussive	III	III E		[52 FR 30055]
2R04ONI666	eucalyptus oil	cough/cold	nasal decongestant	III	III E		[59 FR 43408]
2R04ONI667	eucalyptus oil	external analgesic	counter irritant	I	I	310.545(a)(10)(ii)	
2R04ONI668	eucalyptus oil	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
2R04ONI669	eucalyptus oil	external analgesic	poison ivy/oak/sumac	I	I	310.545(a)(10)(vii)	
2R04ONI670	eucalyptus oil	skin protectant	astringent	II		310.545(a)(18)(ii)	
2R04ONI671	eucalyptus oil	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
2R04ONI672	eucalyptus oil (lozenge)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
2R04ONI673	eucalyptus oil (mouthwash)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
3T8H1794QW	eugenol	external analgesic	analgesic & anesthetic	III	III	310.545(a)(10)(i)	
3T8H1794QW	eugenol	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
3T8H1794QW	eugenol	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
3T8H1794QW	eugenol		relief of oral discomfort		III SE		
3T8H1794QW	eugenol	skin protectant	astringent	II		310.545(a)(18)(ii)	
L13YF113GN	euphorbia pilulifera	cough/cold	bronchodilator	III	III	310.545(a)(6)(iv)	
	fennel acid	digestive aid				310.545(a)(8)(ii)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
	ferric acid	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
UVP74NG1C5	ferric ammonium citrate	weight control		II		310.545(a)(20)	
U38V3ZVV3V	ferric chloride	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
U38V3ZVV3V	ferric chloride	menstrual/diuretic				310.545(a)(24)(i)	
U38V3ZVV3V	ferric chloride	oral health care		IIE			
U38V3ZVV3V	ferric chloride	skin protectant	insect bites/stings		II	310.545(a)(18)(v)(A)	
QK8899250F	ferric pyrophosphate	weight control			II	310.545(a)(20)	
3QJ8WS6V8H	ferric subsulfate (Monsel's solution)	skin protectant	astringent	II		310.545(a)(18)(ii)	
R5L488RY0Q	ferrous fumarate	weight control		II		310.545(a)(20)	
U1B11I423Z	ferrous gluconate	weight control		II		310.545(a)(20)	
39R4TAN1VT	ferrous sulfate	menstrual/diuretic				310.545(a)(24)(i)	
39R4TAN1VT	ferrous sulfate (iron)	weight control		II		310.545(a)(20)	
4110YT348C	flax seed	weight control		II		310.545(a)(20)	
80OFG3WPYD	fluorosalan	antimicrobial		IIS			
935E97BOY8	folic acid	weight control		II		310.545(a)(20)	
1HG84L3525	formaldehyde solution	relief of oral discomfort		IIIIE			
0YIW783RG1	formic acid	pediculicide				310.545(a)(25)(i)	
S2D77IH61R	frangula	laxative	stimulant laxative	III		310.545(a)(12)(iv)(A)	
6YSS42VSEV	fructose	overindulgence in a	inebriation minimizer	IIIIE			[48 FR 32873]
6YSS42VSEV	fructose	weight control		II		310.545(a)(20)	
BIA2SO6F5B	galega	digestive aid				310.545(a)(8)(ii)	
7556HJ7587	gamboge	laxative	stimulant laxative	II		310.545(a)(12)(iv)(A)	
V1V998DC17	garlic, dehydrated	digestive aid		II	II	310.545(a)(8)(i)	
2G86QN327L	gelatin	ophthalmic	demulcents	I	I	349.12(c)	
2G86QN327L	gelatin	oral health care	demulcents	I	I		
J4Z741D605	gentian violet	oral health care		IIE			
J4Z741D605	gentian violet	anthelmintic		I	II		
S72O3284MS	gentiana lutea (gentian)	menstrual/diuretic				310.545(a)(24)(i)	
C5529G5JPQ	ginger	digestive aid				310.545(a)(8)(ii)	
ZQH6VH092Z	ginseng	nighttime sleep aid		II			
ZQH6VH092Z	ginseng	stimulant		IIE			[39 FR 6104]
3KX376GY7L	glutamic acid hydrochloride	digestive aid	stomach acidifier	II	II	310.545(a)(8)(i)	
PDC6A3C0OX	glycerin	anorectal	protectant	I(e)	I(e)	346.14(a)(3)	
PDC6A3C0OX	glycerin	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
PDC6A3C0OX	glycerin	laxative	hyperosmotic	I			
PDC6A3C0OX	glycerin	ophthalmic	demulcents	I	I	349.12(d)(1)	
PDC6A3C0OX	glycerin	oral health care		I			
PDC6A3C0OX	glycerin	otic		IIIIE			[51 FR 28660]
PDC6A3C0OX	glycerin	skin protectant	diaper rash	I	IIIIE	310.545(a)(18)(iii)	
PDC6A3C0OX	glycerin	skin protectant	fever blister/cold sore		I		
PDC6A3C0OX	glycerin	skin protectant	insect bites/stings		IIE	310.545(a)(18)(vi)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
PDC6A3C0OX	glycerin	skin protectant		I	I	347.10(h)	
PDC6A3C0OX	glycerine and anhydrous glycerine	otic				310.545(a)(15)(ii)	
PDC6A3C0OX	glycerine and anhydrous glycerine	skin protectant	diaper rash		III	310.545(a)(18)(iii)	
PDC6A3C0OX	glycerine and anhydrous glycerine	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
A886B5N5IM	glyceryl aminobenzoate (lisadimate, glyceryl PABA)	sunscreen		I	I	310.545(a)(29)	64 FR 27670
230OU9XXE4	glyceryl stearate	skin protectant	insect bites/stings w/ sales less than \$25,000			310.545(a)(18)(v)(B)	
230OU9XXE4	glyceryl stearate	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000			310.545(a)(18)(vi)(B)	
230OU9XXE4	glyceryl stearate	skin protectant	w/ sales less than \$25,000			310.545(a)(18)(i)(B)	
TE7660XO1C	glycine	antidiarrheal		II	II	310.545(a)(3)(i)	
TE7660XO1C	glycine	digestive aid				310.545(a)(8)(ii)	
TE7660XO1C	glycine (aminoacetic acid)	antacid			I	331.11(f)	
	glycol salicylate	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
	glycol salicylate	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
61ZBX54883	glycyrrhiza (licorice)	menstrual/diuretic				310.545(a)(24)(i)	
5IE62321P4	gramicidin	first aid antibiotic			III		
495W7451VQ	guaifenesin	cough/cold	expectorant		III	341.18	
E89I1637KE	guar gum	laxative	bulk laxative		III	310.545(a)(12)(i)	
E89I1637KE	guar gum	weight control			III	310.545(a)(20)	
AIU7053OWL	haloprogin	antifungal		I	I	333.210(b)	
8334LX7S21	hard fat	anorectal	protectant			346.14(a)(4)	
8334LX7S21	hard fat	skin protectant				347.10(i)	
	hectorite	digestive aid				310.545(a)(8)(ii)	
	hectorite	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
	hectorite	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
	hemicellulase	digestive aid		III	III	310.545(a)(8)(i)	
IWW5FV6NK2	hexachlorophene	antimicrobial					[37 FR 20163]
R9QTBE82N	hexylresorcinol	antimicrobial		I			
R9QTBE82N	hexylresorcinol	antimicrobial			I		
R9QTBE82N	hexylresorcinol	antimicrobial			II		
R9QTBE82N	hexylresorcinol	antimicrobial			III		
R9QTBE82N	hexylresorcinol	antimicrobial			III		
R9QTBE82N	hexylresorcinol	antimicrobial			III		
R9QTBE82N	hexylresorcinol	antimicrobial			III		
R9QTBE82N	hexylresorcinol	antimicrobial			III		
R9QTBE82N	hexylresorcinol	antimicrobial			III		
R9QTBE82N	hexylresorcinol	external analgesic	analgesic & anesthetic	III	III	310.545(a)(10)(i)	
R9QTBE82N	hexylresorcinol	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
R9QTBE82N	hexylresorcinol	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
R9QTBE82N	hexylresorcinol	oral health care	anesthetic/analgesic	I	I		
3POA0Q644U	histamine dihydrochloride	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
4QD397987E	histidine	weight control			II	310.545(a)(20)	
68JRS2HC1C	homatropine methylbromide	antidiarrheal		III	III	310.545(a)(3)(i)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
68JRS2HC1C	homatropine methylbromide	digestive aid		II/III	III	310.545(a)(8)(i)	
68JRS2HC1C	homatropine methylbromide	menstrual/diuretic	muscle relaxant	II	II	310.545(a)(24)(i)	
V06SV4M95S	homosalate	sunscreen		I	I	352.10(f)	
Y9H1V576FH	honey	skin protectant	astringent	II		310.545(a)(18)(ii)	
7A72MUN24Z	horehound	cough/cold	antitussive	III	III		[52 FR 30054]
7A72MUN24Z	horehound	cough/cold	expectorant			310.545(a)(6)(iii)	
7A72MUN24Z	horehound	oral health care	expectorant	III			
SC52PT1846	horsetail	digestive aid				310.545(a)(8)(ii)	
9P2U39H18W	huckleberry	digestive aid				310.545(a)(8)(ii)	
658O6T0WXZ	hydrastis	anorectal	antiseptic	II(e,i)	II(e,i)	310.545(a)(26)(ii)	
658O6T0WXZ	hydrastis	anorectal	counterirritant	II(e,i)	II(e,i)	310.545(a)(26)(iv)	
S1EFO94F35	hydrastis canadensis	weight control			II	310.545(a)(20)	
ZW3Z11D0JV	hydrastis canadensis (golden seal)	digestive aid				310.545(a)(8)(ii)	
ZW3Z11D0JV	hydrastis canadensis (golden seal)	menstrual/diuretic		II	II	310.545(a)(24)(i)	
1E8C2W13Z0	hydrastis fluid extract	digestive aid				310.545(a)(8)(ii)	
	hydrate magnesium aluminate activated sulfate	antacid				331.11(g)(1)	
QTT17582CB	hydrochloric acid	digestive aid				310.545(a)(8)(ii)	
NO70W886KK	hydrocodone bitartrate	cough/cold	antitussive	II	II		[52 FR 30054]
WI4X0X7BPJ	hydrocortisone	external analgesic		I	I		
WI4X0X7BPJ	hydrocortisone (0.25-5%)	external analgesic		I	I		
WI4X0X7BPJ	hydrocortisone (0.5-1%)	external analgesic			III		
WI4X0X7BPJ	hydrocortisone (combination)	anorectal				310.545(a)(26)(xi)	
3X7931PO74	hydrocortisone acetate	external analgesic		I	I		
3X7931PO75	hydrocortisone acetate	external analgesic		I	I		
3X7931PO76	hydrocortisone acetate (0.25-5.0%)	external analgesic		I	I		
3X7931PO77	hydrocortisone acetate (0.25%-0.5%)	external analgesic		I	I		
	hydrocortisone preparations	dandruff		III	IS		
RGL5YE86CZ	hydrogen fluoride	anticaries		NC	III	310.545(a)(2)(i)	
BBX060AN9V	hydrogen peroxide	antimicrobial			I		
BBX060AN9V	hydrogen peroxide	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
BBX060AN9V	hydrogen peroxide	oral health care	wound cleansing	I	I		
BBX060AN9V	hydrogen peroxide	oral health care			III		
BBX060AN9V	hydrogen peroxide	oral health care			III		
BBX060AN9V	hydrogen peroxide	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
BBX060AN9V	hydrogen peroxide and povidone iodine	gingivitis/plaque			III		
BBX060AN9V	hydrogen peroxide and sodium bicarbonate	gingivitis/plaque			III		
BBX060AN9V	hydrogen peroxide, sodium citrate, sodium lauryl sulfate, and zinc ch	gingivitis/plaque			III		
XV74C1N1AE	hydroquinone	skin bleach			I		
	hydroxyethylcellulose	ophthalmic	demulcents	I	I	349.12(a)(2)	
273FM27VK1	hydroxypropyl methylcellulose	ophthalmic	demulcents	I	I		
F2R8V82B84	hyocystamine sulfate	antidiarrheal		III	III	310.545(a)(3)(i)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
F2R8V82B84	hyoscyamine sulfate	menstrual/diuretic				310.545(a)(24)(i)	
3NXW29V3WO	hypromellose	ophthalmic	demulcents		I	349.12(a)(3)	
WK2XYI10QM	ibuprofen	internal analgesic			I		[67 FR 54139]
WK2XYI10QM	ibuprofen	internal analgesic			I		[67 FR 54139]
	ichthammol	corn/callus remover		II	IISE		[55 FR 33261]
SY15A62UPX	impatiens biflora tincture	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
SY15A62UPX	impatiens biflora tincture	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
969IQC5YJU	infusion of rose petals	ophthalmic	astringent	III	III	310.545(a)(21)(iii)	
4L6452S749	inositol	weight control			II	310.545(a)(20)	
	iodides (calcium iodide anyhydrous, hydroidic acid syrup, iodized lime, potassium iodide, potassium iodate, potassium iodide topical solution, sodium iodide, sodium iodate, sodium iodide topical solution)	cough/cold	expectorant			310.545(a)(6)(iii)	
9679TC07X4	iodine	corn/callus remover		II	IISE		[55 FR 33261]
9679TC07X5	iodine	digestive aid				310.545(a)(8)(ii)	
9679TC07X6	iodine	oral health care			IISE		
9679TC07X7	iodine	wart remover		II	IISE		[55 FR 33254]
9679TC07X8	iodine	weight control			II	310.545(a)(20)	
	iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IISE		
	iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IISE		
	iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IISE		
	iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IISE		
	iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IISE		
	iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IISE		
	iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IISE		
	iodine complex/phosphate ester of alkylaryloxy polyethylene	antimicrobial			IISE		
9679TC07X10	iodine tincture	antimicrobial			IISE		
9679TC07X11	iodine tincture	antimicrobial			IISE		
9679TC07X4	iodine tincture	antimicrobial		I			
9679TC07X5	iodine tincture	antimicrobial		I			
9679TC07X6	iodine tincture	antimicrobial		IIIS			
9679TC07X7	iodine tincture	antimicrobial		IIIS			
9679TC07X8	iodine tincture	antimicrobial		IIISE			
9679TC07X9	iodine tincture	antimicrobial		IIS			
9679TC07X4	iodine topical solution	antimicrobial		I			
V30V6H1QX4	idoantipyrine (idopyrine)	internal analgesic		II	II	310.545(a)(23)(i)	
62I3C8233L	ippecac	cough/cold	expectorant			310.545(a)(6)(iii)	
62I3C8233L	ippecac fluidextract	cough/cold	expectorant	II		310.545(a)(6)(iii)	
62I3C8233L	ippecac fluidextract	poison treatment		II		310.545(a)(16)	
62I3C8233L	ippecac syrup	cough/cold	expectorant	III		310.545(a)(6)(iii)	
62I3C8233L	ippecac syrup	emetic		I		337.10	
62I3C8233L	ippecac syrup	poison treatment		I			
62I3C8233L	ippecac tincture	poison treatment		II		310.545(a)(16)	
	ipomea	laxative	stimulant laxative	II		310.545(a)(12)(iv)(A)	
	iron ox bile	digestive aid				310.545(a)(8)(ii)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
1K09F3G675	iron oxide	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
1K09F3G675	iron oxide	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
	isobornyl thiocycanoacetate	pediculicide		II	II	310.545(a)(25)(i)	
04Y7590D77	isoleucine	weight control			II	310.545(a)(20)	
ND2M416302	isopropyl alcohol	alcohols (topical)		I	I		
ND2M416303	isopropyl alcohol	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
ND2M416304	isopropyl alcohol	mercury			I		
ND2M416305	isopropyl alcohol	otic				344.12	
ND2M416306	isopropyl alcohol	otic				310.545(a)(15)(ii)	
ND2M416307	isopropyl alcohol	skin protectant	astringent	II		310.545(a)(18)(ii)	
ND2M416308	isopropyl alcohol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
8CRQ2TH63M	isopropyl palmitate	skin protectant	insect bites/stings w/ sales less than \$25,000			310.545(a)(18)(v)(B)	
8CRQ2TH63M	isopropyl palmitate	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000			310.545(a)(18)(vi)(B)	
8CRQ2TH63M	isopropyl palmitate	skin protectant	w/ sales less than \$25,000			310.545(a)(18)(i)(B)	
4UDO46YBK2	jalap	laxative	stimulant laxative		II	310.545(a)(12)(iv)(A)	
XK4IUX8MNB	johnswort	digestive aid				310.545(a)(8)(ii)	
YNW2QPG8YK	juniper oil (oil of juniper)	menstrual/diuretic		II	II	310.545(a)(24)(i)	
	juniper tar	anorectal	analgesic, anesthetic, antipruritic	III(e,i)	I(e)	346.16(b)	
	juniper tar	dandruff		III	III	310.545(a)(7)	
	juniper tar	digestive aid				310.545(a)(8)(ii)	
	juniper tar	external analgesic		I	I		
	juniper, potassium extract	weight control			II	310.545(a)(20)	
24H4NWX5C0	kaolin	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(5)	
24H4NWX5C0	kaolin	antidiarrheal		III	III	335.10(b)	
24H4NWX5CO	kaolin	skin protectant	diaper rash		I		
24H4NWX5CO	kaolin	skin protectant		I	I	347.10(j)	
24H4NWX5CO	kaolin, colloidal	digestive aid				310.545(a)(8)(ii)	
	karaya gum	laxative		I			
	karaya gum	weight control		III		310.545(a)(20)	
	kelp	weight control		III		310.545(a)(20)	
64Y2IV7284	knotgrass	digestive aid				310.545(a)(8)(ii)	
33X04XA5AT	lactic acid	digestive aid				310.545(a)(8)(ii)	
33X04XA5AT	lactic acid	wart remover		III	III		[55 FR 33254]
	Lactobacillus acidophilis	antidiarrheal		III	III	310.545(a)(3)(i)	
	Lactobacillus bulgaricus	antidiarrheal		III	III	310.545(a)(3)(i)	
J2B2A4N98G	lactose	digestive aid				310.545(a)(8)(ii)	
J2B2A4N98G	lactose	weight control		II		310.545(a)(20)	
7EV65EAW6H	lanolin	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(6)	
7EV65EAW6H	lanolin	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
7EV65EAW6H	lanolin	skin protectant	diaper rash		I		
7EV65EAW6H	lanolin	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
7EV65EAW6H	lanolin	skin protectant	poison ivy/oak/sumac		I	310.545(a)(18)(vi)	
7EV65EAW6H	lanolin	skin protectant				347.10(k)	
	lanolin (in combination)	ophthalmic	emollient	I	I	349.14(a)(2)	
	lanolin alcohols	anorectal	protectant	I(e,i)	III(e,i)	310.545(a)(26)(viii)	
	lanolin nonionic derivatives	ophthalmic		I	I	349.14	
	lanolin, anhydrous (in combination)	ophthalmic	emollient	I	I	349.14(a)(1)	
	lappa extract	anorectal	other	II(e,i)	II(e,i)	310.545(a)(26)(vii)	
	laureth 10S		vaginal contraceptive		III	310.545(a)(28)(i)	
09TM5K0O34	lauryl isoquinolinium bromide	dandruff		III	III	310.545(a)(7)	
9YT4B71U8P	lavender compound, tincture of	digestive aid				310.545(a)(8)(ii)	
TLH4A6LV1W	lawsone (w/ dihydroxyacetone)	sunscreen		I	I	310.545(a)(29)	
RX077P88RY	lead acetate	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
RX077P88RY	lead acetate	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
	lecithin	weight control		II		310.545(a)(20)	
	leptandra extract	anorectal	other	II(e,i)	II(e,i)	310.545(a)(26)(vii)	
GMW67QNF9C	leucine	weight control			II	310.545(a)(20)	
Y24T9BT2Q2	levmetamfetamine	cough/cold	nasal decongestant		I	341.20(b)(1)	inhalant
Y24T9BT2Q2	levmetamfetamine	cough/cold	nasal decongestant		I	341.20(b)(1)	topical
98PI200987	lidocaine	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(f)	
98PI200988	lidocaine	external analgesic	male genital desensitizer		I	348.10(a)(2)	
98PI200989	lidocaine	external analgesic		I	I		
98PI200990	lidocaine	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
98PI200991	lidocaine	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
V13007Z41A	lidocaine hydrochloride	external analgesic		I	I		
V13007Z41A	lidocaine hydrochloride	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
CFN6G1F6YK	linden	digestive aid				310.545(a)(8)(ii)	
	lipase	digestive aid				310.545(a)(8)(ii)	
3NY3SM6B8U	live yeast cell derivative	anorectal	other			310.545(a)(26)(vii)	
3NY3SM6B8U	live yeast cell derivative	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	
3NY3SM6B8U	live yeast cell derivative	skin protectant	insect bites/stings w/ sales less than \$2	III	III	310.545(a)(18)(v)(B)	
3NY3SM6B8U	live yeast cell derivative	skin protectant	poison ivy/oak/sumac w/ sales less than	III	III	310.545(a)(18)(vi)(B)	
3NY3SM6B8U	live yeast cell derivative	skin protectant	w/ sales less than \$25,000	III	III	310.545(a)(18)(i)(B)	
	liver concentrate	weight control		II		310.545(a)(20)	
K3Z4F929H6	lysine	weight control			II	310.545(a)(20)	
	lysine aspirin	internal analgesic				310.545(a)(23)(i)	
JNJ23Q2COM	lysine hydrochloride	digestive aid				310.545(a)(8)(ii)	
JNJ23Q2COM	lysine hydrochloride	weight control		II		310.545(a)(20)	
	magaldrate	antacid		I		331.11(g)(2)	
I38ZP9992A	magnesium	weight control		II		310.545(a)(20)	
6M2P64V0NC	magnesium aluminosilicate	antacid		I		331.11(g)(3)	
6M2P64V0NC	magnesium aluminosilicate	antacid		I		331.11(l)(1)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
6M2P64V0NC	magnesium aluminum silicate	acne				310.545(a)(1)	
0E53J927NA	magnesium carbonate	antacid		I		331.11(g)(4)	
0E53J927NA	magnesium carbonate	overindulgence in alcohol; hangover reliever		I			
RHO26O1T9V	magnesium citrate (oral)	laxative	saline laxative	I			
IFN18A4Y6B	magnesium glycinate	antacid		I		331.11(g)(5)	
NBZ3QY004S	magnesium hydroxide	antacid		I		331.11(g)(6)	
NBZ3QY004S	magnesium hydroxide	digestive aid	antacid	III	I	310.545(a)(8)(i)	
NBZ3QY004S	magnesium hydroxide	laxative	saline laxative	I			
3A3U0GI71G	magnesium oxide	antacid		I		331.11(g)(7)	
3A3U0GI71G	magnesium oxide	weight control		II		310.545(a)(20)	
41728CY7UX	magnesium salicylate	internal analgesic		I	I		
41728CY7UX	magnesium salicylate	menstrual/diuretic	analgesic	I			
DE08037SAB	magnesium sulfate	acne		II	II	310.545(a)(1)	
DE08037SAB	magnesium sulfate	laxative	saline laxative	I			
DE08037SAB	magnesium sulfate	menstrual/diuretic				310.545(a)(24)(i)	
C2E1CI501T	magnesium trisilicate	antacid		I		331.11(g)(8)	
C2E1CI501T	magnesium trisilicate	antacid		I		331.11(l)(2)	
C2E1CI501T	magnesium trisilicate	digestive aid	antacid	III	I	310.545(a)(8)(i)	
C2E1CI501T	magnesium trisilicate	overindulgence in alcohol; hangover reliever		I			
	malt	weight control		II		310.545(a)(20)	
R3NBG8914U	malt soup extract	laxative		I			
7CVR7L4A2D	maltodextrin	weight control		II		310.545(a)(20)	
4Z2OA6A13N	manganese citrate	weight control		II		310.545(a)(20)	
3OWL53L36A	mannitol	digestive aid				310.545(a)(8)(ii)	
3OWL53L36A	mannitol	weight control		II		310.545(a)(20)	
GGO4Y809LO	m-cresol	antifungal				310.545(a)(22)(iv)	
HDP7W44CIO	meclizine hydrochloride	antiemetic		I		336.10(d)	
	menfegol	vaginal contraceptive		I			
L7T10EIP3A	menthol	antifungal		II	II	310.545(a)(22)(ii)	
L7T10EIP3A	menthol	dandruff		III	III	310.545(a)(7)	
L7T10EIP3A	menthol	skin protectant	astringent	II		310.545(a)(18)(ii)	
LT10EIP3A	menthol	anorectal	analgesic, anesthetic, antipruritic		I(e)	346.16(c)	
LT10EIP3A	menthol	anorectal	counterirritant	II(e,i)	II(e,i)	310.545(a)(26)(iv)	
LT10EIP3A	menthol	cough/cold	antitussive		III	341.14(b)(2)	steam inhalation
LT10EIP3A	menthol	cough/cold	antitussive	III	III	341.14(b)(2)	lozenge
LT10EIP3A	menthol	cough/cold	antitussive	III	I	341.14(b)(2)	lozenge
LT10EIP3A	menthol	cough/cold	antitussive	III	I	341.14(b)(2)	topical
LT10EIP3A	menthol	cough/cold	nasal decongestant	III	III		[59 FR 43408]
LT10EIP3A	menthol	external analgesic		I	I		
LT10EIP3A	menthol	oral health care	anesthetic/analgesic	I	I		
LT10EIP3A	menthol	relief of oral discomfort			IIS		

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
LT10EIP3A	menthol	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
LT10EIP3A	menthol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
LT10EIP3A	menthol	wart remover		II	IISE		[55 FR 33254]
LT10EIP3A	menthol (0.1 to 1.0%)	external analgesic		I	I		
LT10EIP3A	menthol (mouthwash)	cough/cold	antihistamine	III	III	310.545(a)(6)(ii)(A)	
L7T10EIP3A	menthol exceeding 1%	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
	menthol/peppermint oil	cough/cold	expectorant			310.545(a)(6)(iii)	
J9QGD60OUZ	meradimate (menthyl anthranilate)	sunscreen		I	I	352.10(h)	
	meralein sodium	oral health care			IISE		
M0T18YH28D	merbromin	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
M0T18YH28D	merbromin	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
M0T18YH28D	merbromin (mercurochrome)	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
	mercufenol chloride (orthochloromercuriphenol, orthohydroxyphenyl)	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
53GH7MZT1R	mercuric chloride	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
53GH7MZT1R	mercuric chloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
53GH7MZT1R	mercuric chloride (bichloride of mercury, mercury chloride)	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
IY191986AO	mercuric oxide, yellow	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
	mercuric salicylate	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
	mercuric sulfide, red	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
FXS1BY2PGL	mercury	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
	mercury oleate	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
	mercury oleate	dandruff		II	II	310.545(a)(7)	
	mercury sulfide	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
	mercury, ammoniated	skin bleach				310.545(a)(17)	
	mercury-containing ingredient	antimicrobial	diaper rash			310.545(a)(27)(ii)	
	mercury-containing ingredients	vaginal contraceptive				310.545(a)(28)(i)	
GJ20H50YF0	metaproterenol sulfate	cough/cold	antihistamine	I	I	310.545(a)(6)(iv)	
KJ5I25TXYL	methapyrilene fumarate	cough/cold	antihistamine	I	II	310.545(a)(6)(i)	
KJ5I25TXYL	methapyrilene fumarate	internal analgesic		III	II	310.545(a)(23)(i)	
KJ5I25TXYL	methapyrilene fumarate	nighttime sleep aid	antihistamine	II	IIS		[54 FR 6826]
00S42N58OM	methapyrilene hydrochloride	cough/cold	antihistamine	I	II	310.545(a)(6)(i)	
00S42N58OM	methapyrilene hydrochloride	external analgesic	analgesic & anesthetic	I	II	310.545(a)(10)(i)	
00S42N58OM	methapyrilene hydrochloride	external analgesic	fever blister/cold sore	I	II	310.545(a)(10)(v)	
00S42N58OM	methapyrilene hydrochloride	external analgesic	poison ivy/oak/sumac	I	II	310.545(a)(10)(vii)	
00S42N58OM	methapyrilene hydrochloride	menstrual/diuretic				310.545(a)(24)(i)	
00S42N58OM	methapyrilene hydrochloride	nighttime sleep aid	antihistamine	II	IIS		[54 FR 6826]
J50OIX95QV	methenamine	menstrual/diuretic				310.545(a)(24)(i)	
AE28F7PNPL	methionine	weight control			II	310.545(a)(20)	
52V8BVV7FX	methoxyphenamine hydrochloride	cough/cold	bronchodilator	I	II	310.545(a)(6)(iv)	
	methoxypolyoxyethyleneglycol 550 laurate	vaginal contraceptive			IIIIE	310.545(a)(28)(i)	
7B1AVU9DJN	methyl nicotinate	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
LAV5U5022Y	methyl salicylate	corn/callus remover		II	IISE		[55 FR 33261]
LAV5U5022Y	methyl salicylate	dandruff		III	III	310.545(a)(7)	
LAV5U5022Y	methyl salicylate	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
LAV5U5022Y	methyl salicylate	oral health care	anesthetic/analgesic	III	III	310.545(a)(14)	
LAV5U5022Y	methyl salicylate	relief of oral discomfort			IISE		
LAV5U5022Y	methyl salicylate	relief of oral discomfort			IISE		
LAV5U5022Y	methyl salicylate	skin protectant	astringent			310.545(a)(18)(ii)	
	methylbenzethonium chloride	antimicrobial			I		
	methylbenzethonium chloride	antimicrobial			I		
	methylbenzethonium chloride	antimicrobial			IIIE		
	methylbenzethonium chloride	antimicrobial			IIISE		
	methylbenzethonium chloride	antimicrobial			IIISE		
	methylbenzethonium chloride	antimicrobial			IIISE		
	methylbenzethonium chloride	antimicrobial			IIISE		
	methylbenzethonium chloride	antimicrobial			IIISE		
	methylbenzethonium chloride	antimicrobial			IIISE		
	methylbenzethonium chloride	corn/callus remover		II	IISE		[55 FR 33261]
	methylbenzethonium chloride	dandruff		III	III	310.545(a)(7)	
4GFU244C4J	methylcellulose	laxative			I		
4GFU244C4J	methylcellulose	ophthalmic	demulcents	I	I	349.12(a)(4)	
4GFU244C4J	methylcellulose	weight control			III		310.545(a)(20)
T42P99266K	methylene blue	menstrual/diuretic					310.545(a)(24)(i)
A2I8C7HI9T	methylparaben	antifungal		III	III	310.545(a)(22)(ii)	
VW4H1CYW1K	miconazole nitrate	antifungal		I	I	333.210(c)	
	mild silver protein	ophthalmic	anti-infective	III	II	310.545(a)(21)(ii)	
917J3173FT	milk solids, dried	antacid			I		331.11(h)
N6K5787QVP	minaeral oil	skin protectant	diaper rash		I		
T5L8T28FGP	mineral oil	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(7)	
T5L8T28FGP	mineral oil	laxative	lubricant		I		
T5L8T28FGP	mineral oil	ophthalmic	emollient	I	I	349.14(b)(2)	
T5L8T28FGP	mineral oil	skin protectant			I		347.10(l)
T5L8T28FGP	mineral oil, light	ophthalmic	emollient	I	I	349.14(b)(1)	
	mono- and di-glycerides	weight control			II		310.545(a)(20)
9936O846LI	mullein	anorectal	other	II(e,i)	II(e,i)	310.545(a)(26)(vii)	
N4G8379626	mustard oil (alltishthiocyanate) (tpoical/inhalant)	cough/cold	nasal decongestant	II	II		
	mycozyme	digestive aid					310.545(a)(8)(ii)
JC71GJ1F3L	myrrh	relief of oral discomfort			IIIE		
JC71GJ1F3L	myrrh tincture	oral health care	astringent	II	II	310.545(a)(14)	
JC71GJ1F3L	myrrh, fluid extract of	digestive aid					310.545(a)(8)(ii)
MZ1131787D	naphazoline hydrochloride	cough/cold	nasal decongestant		I	341.20(b)(6)	
MZ1131787D	naphazoline hydrochloride	cough/cold	nasal decongestant		I	341.20(b)(6)	
MZ1131787D	naphazoline hydrochloride	ophthalmic	vasoconstrictor	I	I	349.18(b)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
MZ1131787D	naphazoline hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(6)	
MZ1131787D	naphazoline hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(6)	
	natural estrogenic horomone	menstrual/diuretic				310.545(a)(24)(i)	
I16QD7X297	neomycin ointment (combination only)	first aid antibiotic			I	333.120	
057Y626693	neomycin sulfate	first aid antibiotic	ointment	I		333.110(d)	
057Y626693	neomycin sulfate cream	first aid antibiotic		I		333.110(e)	
0GG6WIU2KW	nettle	digestive aid				310.545(a)(8)(ii)	
25X518RD4	niacinamide	menstrual/diuretic				310.545(a)(24)(i)	
25X518RD4	niacinamide	nighttime sleep aid		II			
25X518RD4	niacinamide	weight control		II		310.545(a)(20)	
	nickel-pectin	digestive aid				310.545(a)(8)(ii)	
RU6242GP15	nitromersol	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
RU6242GP15	nitromersol	oral health care		I			
nonylphenoxyopoly	nonoxynol 9	vaginal contraceptive					
	nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial		II			
	nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial		II			
	nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial		II			
	nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial		II			
	nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial		II			
	nonylphenoxypoly (ethyleneoxy) ethanol iodine	antimicrobial		II			
	noscapine	cough/cold	antitussive	III	III		[52 FR 30054]
	noscapine hydrochloride	cough/cold	antitussive	III	III		[52 FR 30054]
AEE24M3MQ9	nutmeg oil (oil of nutmeg)	menstrual/diuretic				310.545(a)(24)(i)	
269XH13919	nux vomica extract	digestive aid				310.545(a)(8)(ii)	
BDF1O1C72E	nystatin	antifungal		I	III	310.545(a)(22)(iv)	
	obtundia surgical dressing	external analgesic			II		
	obtundia surgical dressing	skin protectant	insect bites/stings		II		
4Y5P7MUD51	octinoxate (octyl methoxycinnamate; ethylhexyl methoxycinnamate)	sunscreen		I	I	352.10(j)	
4X49Y0596W	octisalate (octyl salicylate; ethylhexyl salicylate)	sunscreen		I	I	352.10(k)	
5A68WGF6WM	octocrylene	sunscreen		I	I	352.10(i)	
7JPC6Y25QS	octoxytol 9	vaginal contraceptive		I		310.545(a)(28)(ii)	
	octyl triazole (ethylhexyl triazole)	sunscreen		NA			
	oil of erigeron	menstrual/diuretic				310.545(a)(24)(i)	
	Opium powder	antidiarrheal		I	III	310.545(a)(3)(i)	
	Opium tincture	antidiarrheal		I	III	310.545(a)(3)(i)	
	organic vegetables	weight control			II	310.545(a)(20)	
E4GA8884NN	orthophosphoric acid	digestive aid				310.545(a)(8)(ii)	
	ox bile	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
	ox bile extract	digestive aid		II	II	310.545(a)(8)(i)	
95OOS7VE0Y	oxybenzone (benzophenone-3)	sunscreen		I	I	352.10(l)	
K89MJ0S5VY	oxymetazoline hydrochloride (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(7)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
K89MJ0S5VY	oxymetazoline hydrochloride (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(7)	
K89MJ0S5VY	oxymetazoline hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(7)	
5UTX5635HP	oxyquinoline	antifungal		III	III	310.545(a)(22)(ii)	
5UTX5635HP	oxyquinoline	antimicrobial			IIISE		
5UTX5635HP	oxyquinoline	oral health care			IIISE		
61VUG75Y3P	oxyquinoline sulfate	antifungal		III	III	310.545(a)(22)(ii)	
61VUG75Y3P	oxyquinoline sulfate	skin protectant	astringent	II		310.545(a)(18)(ii)	
4U7K4N52ZM	oxytetracycline hydrochloride (combination only)	first aid antibiotic	ointment		I	333.120	
77FU10423X	padimate a (5 percent or higher)	sunscreen			IISE		
77FU10423X	padimate a (up to 5 percent)	sunscreen		I	IISE		
Z11006CMUZ	padimate o	sunscreen		I	I	352.10(m)	
UA8U0KJM72	pamabrom	menstrual/diuretic	antihistamine	I	I		
FQ3DRG0N5K	pancreatin	digestive aid	exocrine pancreatic insufficiency	II/III	I	310.545(a)(8)(i)	
FQ3DRG0N5K	pancreatin	weight control			II	310.545(a)(20)	
FQ3DRG0N5K	pancrelipase	digestive aid	exocrine pancreatic insufficiency	II/III	I	310.545(a)(8)(i)	
WV9CM0O67Z	panthenol	corn/callus remover		II	IISE		[55 FR 33261]
WV9CM0O67Z	panthenol	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
WV9CM0O67Z	panthenol	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
WV9CM0O67Z	panthenol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
19FHK2737	pantothenic acid	weight control			II	310.545(a)(20)	
A236A06Y32	papain	digestive aid		II	II	310.545(a)(8)(i)	
A236A06Y32	papain	weight control			II	310.545(a)(20)	
KU94FIY6JB	papaya enzymes	weight control			II	310.545(a)(20)	
KU94FIY6JB	papaya, natural	digestive aid				310.545(a)(8)(ii)	
3JJ4O33LAY	para-chloromercuriphenol	antimicrobial	diaper rash			310.545(a)(27)(ii)	
3JJ4O33LAY	para-chloromercuriphenol	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
I9O0E3H2ZE	paraffin	ophthalmic	emollient	I	I	349.14(b)(3)	
	paregoric	antidiarrheal		I	III	310.545(a)(3)(i)	
414P5USJ7F	parethoxycaine hydrochloride	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
68E52E5J67	parethoxycaine hydrochloride	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
58FMD0Q0EV	parsley	menstrual/diuretic				310.545(a)(24)(i)	
SY49TH8VUA	passion flower extract	nighttime sleep aid		II			
89NA02M4RX	pectin	antidiarrheal	w/ sales less than \$25,000	III	III	310.545(a)(3)(ii)	
89NA02M4RX	pectin	digestive aid				310.545(a)(8)(ii)	
89NA02M4RX	pectin	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
89NA02M4RX	pectin	oral health care	demulcents	I	I		
V95R5KMY2B	peppermint	digestive aid				310.545(a)(8)(ii)	
V95R5KMY2B	peppermint oil	cough/cold	antitussive		IIIIE		[52 FR 30054]
V95R5KMY2B	peppermint oil	cough/cold	nasal decongestant		IIIIE		[59 FR 43408]
V95R5KMY2B	peppermint oil	cough/cold	nasal decongestant		IIIIE		[59 FR 43408]
V95R5KMY2B	peppermint oil	cough/cold	nasal decongestant		IIIIE		[59 FR 43408]

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
339NCG44TV	phenol	antimicrobial			IIISE		
339NCG44TV	phenol	antimicrobial			IIS		
339NCG44TV	phenol	antimicrobial			IIS		
339NCG44TV	phenol	antimicrobial			IIS		
339NCG44TV	phenol	antimicrobial			IIS		
339NCG44TV	phenol	antimicrobial			IIS		
339NCG44TV	phenol	antimicrobial			IIS		
339NCG44TV	phenol	antimicrobial			IIS		
339NCG44TV	phenol	antimicrobial			IIS		
339NCG44TV	phenol	dandruff		III	III	310.545(a)(7)	
339NCG44TV	phenol	external analgesic		I	I		
339NCG44TV	phenol	oral health care	anesthetic/analgesic	I	I		
339NCG44TV	phenol	relief of oral discomfort			I		
339NCG44TV	phenol	relief of oral discomfort			IIISE		
339NCG44TV	phenol	skin protectant	astringent	II		310.545(a)(18)(ii)	
339NCG44TV	phenol	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
339NCG44TV	phenol	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
4NC0T56V35	phenolate sodium	acne		II	II	310.545(a)(1)	
4NC0T56V35	phenolate sodium	antifungal		II	III	310.545(a)(22)(ii)	
4NC0T56V35	phenolate sodium	dandruff		III	III	310.545(a)(7)	
4NC0T56V35	phenolate sodium	external analgesic		I	I		
4NC0T56V35	phenolate sodium	oral health care	anesthetic/analgesic	I	I		
4NC0T56V35	phenolate sodium	relief of oral discomfort			I		
4NC0T56V35	phenolate sodium	relief of oral discomfort			IIISE		
6QK969R2IF	phenolphthalein	laxative	stimulant laxative		I	310.545(a)(12)(iv)(B)	
YRC253429Q	phenoxyacetic acid	corn/callus remover		III	IIIIE		[55 FR 33261]
28A37T47QO	phenyl salicylate	corn/callus remover		II	II		
28A37T47QO	phenyl salicylate	acne		II	II	310.545(a)(1)	
28A37T47QO	phenyl salicylate	antiemetic			II		
28A37T47QO	phenyl salicylate	antifungal		III	III	310.545(a)(22)(ii)	
28A37T47QO	phenyl salicylate	menstrual/diuretic				310.545(a)(24)(i)	
28A37T47QO	phenyl salicylate (salo)	antidiarrheal		III	III	310.545(a)(3)(i)	
47E5O17Y3R	phenylalanine	weight control			II	310.545(a)(20)	
27O3Q5ML57	phenylephrine bitartrate (effervescent)	cough/cold	nasal decongestant			341.20(a)(4)	
04JA59TNSJ	phenylephrine hydrochloride	anorectal	vasoconstrictor	I		346.12(d)	
04JA59TNSJ	phenylephrine hydrochloride	cough/cold	nasal decongestant		I	341.20(a)(1)	oral
04JA59TNSJ	phenylephrine hydrochloride	ophthalmic	vasoconstrictor	III	III	310.545(a)(21)(v)	
04JA59TNSJ	phenylephrine hydrochloride	oral health care		III			
04JA59TNSJ	phenylephrine hydrochloride (0.08 to 0.2%)	ophthalmic	vasoconstrictor	I	I	349.18(c)	
04JA59TNSJ	phenylephrine hydrochloride (aqueous)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
04JA59TNSJ	phenylephrine hydrochloride (aqueous)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
04JA59TNSJ	phenylephrine hydrochloride (aqueous)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
04JA59TNSJ	phenylephrine hydrochloride (aqueous)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
04JA59TNSJ	phenylephrine hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
04JA59TNSJ	phenylephrine hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
04JA59TNSJ	phenylephrine hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(8)	
OSX88361UX	phenylmercuric acetate	vaginal contraceptive		IIS		310.545(a)(28)(i)	
CG8692ZN14	phenylmercuric nitrate	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
CG8692ZN14	phenylmercuric nitrate	vaginal contraceptive		IIS		310.545(a)(28)(i)	
B48FTC099P	phenylpropanolamine bitartrate	cough/cold	nasal decongestant	I			
8D5I63UE1Q	phenylpropanolamine hydrochloride	oral health care		III			
8D5I63UE1Q	phenylpropanolamine hydrochloride	weight control			I/IIS		
8D5I63UE1Q	phenylpropanolamine hydrochloride (oral)	cough/cold	nasal decongestant	I			
8D5I63UE1Q	phenylpropanolamine hydrochloride (topical)	cough/cold	nasal decongestant	III			
	phenylpropanolamine maleate	cough/cold	nasal decongestant	I			
8UE48MJH8M	phenyltoloxamine citrate	internal analgesic			IIIIE		
8UE48MJH8M	phenyltoloxamine citrate	menstrual/diuretic	antihistamine	NA	III		
8UE48MJH8M	phenyltoloxamine dihydrogen citrate	cough/cold	antihistamine			310.545(a)(6)(i)	
8UE48MJH8M	phenyltoloxamine dihydrogen citrate	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
8UE48MJH8M	phenyltoloxamine dihydrogen citrate	internal analgesic		III	III		
8UE48MJH8M	phenyltoloxamine dihydrogen citrate	nighttime sleep aid	antihistamine	III	IISE		[54 FR 6826]
8UE48MJH8M	phenyltoloxamine dihydrogen citrate	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
	phenyltoloxamine hydrochloride	cough/cold	antihistamine			310.545(a)(6)(i)	
	phosphorated carbohydrate	antiemetic		III			
E4GA8884NN	phosphoric acid	anticaries		II	NC	310.545(a)(2)(ii)	
27YLUT5U4W	phosphorus	weight control		II		310.545(a)(20)	
11E6VI8VEG	phytolacca	weight control		II		310.545(a)(20)	
ZLT174DL7U	picrotoxin	pediculicide		II	II	310.545(a)(25)(i)	
	pine tar	dandruff		III	III	310.545(a)(7)	
	pine tar preparations (extract white pine compound, pine tar, syrup or tincture of white pine)	cough/cold	expectorant	III		310.545(a)(6)(iii)	
	pineapple enzymes	weight control		II		310.545(a)(20)	
63KP7FXF2I	piperazine citrate	anthelmintic		II	IIS		[51 FR 27758]
Q2RHOXR1MB	piperacaine hydrochloride	ophthalmic	anesthetic	II	II	310.545(a)(21)(i)	
LWK91TU9AH	piperonyl butoxide (combination)	pediculicide				310.545(a)(25)(ii)	
	pipsissewa	menstrual/diuretic		II	II	310.545(a)(24)(i)	
58JV0P12FY	piscidia erythrina	menstrual/diuretic	botanical/vegetable herb	II	II	310.545(a)(24)(i)	
	plantago ovata husks	laxative	bulk laxative	I			
9C60Y73166	plantago seed	laxative	bulk laxative	I			
9C60Y73166	plantago seed	weight control		III		310.545(a)(20)	
9C60Y73166	plantago seed husks [see psyllium seed husks]	laxative		IISE			
9C60Y73166	plantago seed, blond [see plantago seed]	laxative		IISE			
	podophyllum resin (podophyllin)	laxative	stimulant laxative	II		310.545(a)(12)(iv)(A)	
	poloxamer	laxative	stool softener	III		310.545(a)(12)(iii)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
85H0HZU99M	povidone-iodine	antimicrobial			III	310.545(a)(7)	
85H0HZU99M	povidone-iodine	antimicrobial			III		
85H0HZU99M	povidone-iodine	antimicrobial			III		
85H0HZU99M	povidone-iodine	antimicrobial			III		
85H0HZU99M	povidone-iodine	dandruff			III		
85H0HZU99M	povidone-iodine	oral health care			III		
	povidone-vinylacetate copolymers	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
	povidone-vinylacetate copolymers	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
88AYB867L5	pramoxine hydrochloride	anorectal	local anesthetic	I(e),III(i)	I(e),III(i)	346.10(g)	
88AYB867L5	pramoxine hydrochloride	external analgesic		I	I		
88AYB867L5	pramoxine hydrochloride	skin protectant	diaper rash				
88AYB867L5	pramoxine hydrochloride (combination)	anorectal				310.545(a)(26)(xi)	
70FD1KFU70	precipitated sulfur	anorectal	keratolytic	III(e),II(i)	III(e),II(i)	310.545(a)(26)(v)	
	prolase	digestive aid				310.545(a)(8)(ii)	
JHU490RVYR	propionic acid	antifungal			III	310.545(a)(22)(ii)	
6DC9Q167V3	propylene glycol	ophthalmic	demulcents	I	I	349.12(d)(5)	
6DC9Q167V3	propylene glycol	pediculicide		II	II	310.545(a)(25)(i)	
LQU92IU8LL	propylhexedrine	cough/cold	nasal decongestant	I	I	341.20(b)(9)	inhalant
Z8IX2SC1OH	propylparaben	antifungal		III	III	310.545(a)(22)(ii)	
	protease	digestive aid				310.545(a)(8)(ii)	
	protein hydrolysate	skin protectant	diaper rash		III	310.545(a)(18)(iii)	
S8O01I9YLZ	prune concentrate dehydrate	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
S8O01I9YLZ	prune powder	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
6V9V2RYJ8N	pseudoephedrine hydrochloride	cough/cold	bronchodilator	II	II	310.545(a)(6)(iv)	
6V9V2RYJ8N	pseudoephedrine hydrochloride	cough/cold	nasal decongestant	I	I	341.20(a)(2)	oral
Y9DL7QPE6B	pseudoephedrine sulfate	cough/cold	bronchodilator	II	II	310.545(a)(6)(iv)	
Y9DL7QPE6B	pseudoephedrine sulfate	cough/cold	nasal decongestant	I	I	341.20(a)(3)	oral
Y9DL7QPE6B	pseudoephedrine sulfate (oral)	cough/cold	nasal decongestant	I	I		
9C60Y73166	psyllium (hemicellulose) [see plantago seed]	laxative			II		
	psyllium hydrophilic mucilloid	laxative			I		
9C60Y73166	psyllium seed	laxative			I		
	psyllium seed (blond)	laxative			I		
	psyllium seed husks	laxative			I		
	psyllium (hemicellulose)	laxative	bulk laxative		I		
0462U14DUI	p-t-butyl-m-cresol	skin protectant	astringent			310.545(a)(18)(ii)	
81BK194Z5M	pyrantel pamoate	anthelmintic		I	I	357.11	
ZUM06L90GV	pyrethrum extract (combination)	pediculicide	aresol		I	310.545(a)(25)(ii)	
ZUM06L90GV	pyrethrum extract (combination)	pediculicide	non-aresol	I	I	358.61	
68Y4CF58BV	pyridoxine hydrochloride	menstrual/diuretic	vitamine	III	III		
68Y4CF58BV	pyridoxine hydrochloride	skin protectant	fever blister/cold sore			310.545(a)(18)(iv)	
68Y4CF58BV	pyridoxine hydrochloride (vitamin B6)	weight control			II	310.545(a)(20)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
R35D29L3ZA	pyrilamine maleate	acne		II	II	310.545(a)(1)	
R35D29L3ZA	pyrilamine maleate	cough/cold	antihistamine	I	I	341.12(k)	
R35D29L3ZA	pyrilamine maleate	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
R35D29L3ZA	pyrilamine maleate	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
R35D29L3ZA	pyrilamine maleate	internal analgesic		III	III	310.545(a)(23)(i)	
R35D29L3ZA	pyrilamine maleate	menstrual/diuretic	antihistamine	I	IIISE		
R35D29L3ZA	pyrilamine maleate	nighttime sleep aid	antihistamine	III	IIISE		[54 FR 6826]
R35D29L3ZA	pyrilamine maleate	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
R35D29L3ZA	pyrilamine maleate	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
R35D29L3ZA	pyrilamine maleate	skin protectant	insect bites/stings		IISE	310.545(a)(18)(v)(A)	
R35D29L3ZA	pyrilamine maleate	skin protectant	poison ivy/oak/sumac				
R953O2RHZ5	pyrithione zinc	dandruff	dandruff (wash-off)	I	I	358.710(a)(2)	
R953O2RHZ6	pyrithione zinc	dandruff	dandruff (leave-on)	I	I	358.710(a)(3)	
R953O2RHZ7	pyrithione zinc	dandruff	seborrheic dermatitis (wash-off)	I	I	358.710(b)(2)	
R953O2RHZ8	pyrithione zinc	dandruff	seborrheic dermatitis (leave-on)	I	I	358.710(b)(3)	
A7V27PHC7A	quinine	antimalarial				310.547	
A7V27PHC7A	quinine	internal analgesic		II	II	310.545(a)(23)(i)	
73JWT2K6T3	racemethionine	skin protectant	diaper rash		III	310.545(a)(18)(iii)	
43SK4LA07D	racephedrine hydrochloride	cough/cold	bronchodilator		I	341.16(f)	
43SK4LA07D	racephedrine hydrochloride (oral/topical)	cough/cold	nasal decongestant	I	I	310.545(a)(6)(ii)(B)	
43SK4LA07D	racepinephrine hydrochloride	cough/cold	bronchodilator	I	I	341.16(g)	inhalation
43SK4LA07D	racepinephrine hydrochloride	cough/cold	bronchodilator	I	I	341.16(g)	rubber bulb
	red petrolatum	sunscreen		I	I	310.545(a)(29)	
	reosote	relief of oral discomfort			IISE		
YUL4LO94HK	resorcinol	anorectal	antiseptic	III(e),II(i)	III(e),II(i)	310.545(a)(26)(ii)	
YUL4LO94HK	resorcinol	anorectal	keratolytic	I(e),II(i)	I(e),II(i)	346.20(b)	
YUL4LO94HK	resorcinol	antifungal		II	II	310.545(a)(22)(ii)	
YUL4LO94HK	resorcinol	antimicrobial			IISE		
YUL4LO94HK	resorcinol	dandruff		II	II	310.545(a)(7)	56 FR 63567
YUL4LO94HK	resorcinol	external analgesic		I	I		
YUL4LO94HK	resorcinol	skin protectant	diaper rash				
YUL4LO94HK	resorcinol (as single ingredient only)	acne		III	II	310.545(a)(1)	
YUL4LO94HK	resorcinol (when combined with sulfur)	acne				333.310(b)	
YUL4LO94HK	resorcinol monoacetate (as single ingredient only)	acne		III	II	310.545(a)(1)	
YUL4LO94HK	resorcinol monoacetate (when combined with sulfur)	acne				333.310(c)	
G280W4MW6E	rhubarb fluid extract	digestive aid				310.545(a)(8)(ii)	
G280W4MW6E	rhubarb fluidextract	antidiarrheal	w/ sales less than \$25,000	II	II	310.545(a)(3)(ii)	
	rhubarb, Chinese	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
TLM2976OFR	riboflavin	menstrual/diuretic				310.545(a)(24)(i)	
TLM2976OFR	riboflavin	weight control		II		310.545(a)(20)	
	rice polishings	weight control			II	310.545(a)(20)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
6NAF1689IO	sabadilla, alkaloids	pediculicide		II	II	310.545(a)(25)(i)	
FST467XS7D	saccharin	weight control			II	310.545(a)(20)	
U27K0H1H2O	sage oil	skin protectant	astringent	II		310.545(a)(18)(ii)	
FA1N0842KB	salicyl alcohol	oral health care		I	I		
EM8BM710ZC	salicylamide	external analgesic	analgesic & anesthetic	III	III	310.545(a)(10)(i)	
EM8BM710ZC	salicylamide	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
EM8BM710ZC	salicylamide	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
EM8BM710ZC	salicylamide	internal analgesic		III	III SE		
EM8BM710ZC	salicylamide	menstrual/diuretic			III SE		
EM8BM710ZC	salicylamide	nighttime sleep aid		II	II E		[54 FR 6826]
O414PZ4LPZ	salicylic acid	acne		III	I	333.310(d)	
O414PZ4LPZ	salicylic acid	antifungal		III	III	310.545(a)(22)(ii)	
O414PZ4LPZ	salicylic acid	corn/callus remover	collodoin-like vehicle	I	I	358.510(b)	
O414PZ4LPZ	salicylic acid	corn/callus remover	plaster vehicle	I	I	358.510(a)	
O414PZ4LPZ	salicylic acid	dandruff	dandruff	I	I	358.710(a)(4)	
O414PZ4LPZ	salicylic acid	dandruff	psoriasis	I	I	358.710(c)(2)	
O414PZ4LPZ	salicylic acid	dandruff	seborrheic dermatitis	I	I	358.710(b)(4)	
O414PZ4LPZ	salicylic acid	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
O414PZ4LPZ	salicylic acid	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
O414PZ4LPZ	salicylic acid	wart remover	collodoin-like vehicle	I	I	358.110(b)	
O414PZ4LPZ	salicylic acid	wart remover	karaya gum, glycol plaster vehicle	I	I	358.110(c)	
O414PZ4LPZ	salicylic acid	wart remover	plaster vehicle		II SE	358.110(a)	
O414PZ4LPZ	salicylic acid (over 2 up to 5%)	acne		III	III	310.545(a)(1)	
V9MO595C9I	salsalate	internal analgesic		III	III	310.545(a)(23)(i)	
N9288CD508	sanguinaria extract	gingivitis/plaque			III E		
J7WWH9M8QS	saw palmetto	menstrual/diuretic				310.545(a)(24)(i)	
	scopolamine aminoxide hydrobromide	nighttime sleep aid	scopolamine compound	II	IIS		[54 FR 6826]
451IFR0GXB	scopolamine hydrobromide	antidiarrheal		II	II	310.545(a)(3)(i)	
451IFR0GXB	scopolamine hydrobromide	nighttime sleep aid	scopolamine compound	II	IIS		[54 FR 6826]
	sea minerals	weight control			II	310.545(a)(20)	
Z69D9E381Q	selenium sulfide	dandruff	dandruff	I	I	358.710(a)(5)	
Z69D9E381Q	selenium sulfide	dandruff	seborrheic dermatitis	I	I	358.710(b)(5)	
Z69D9E381Q	selenium sulfide, micronized	dandruff	dandruff	I	I	358.710(a)(6)	
5WS1632J8W	senecio aureus	menstrual/diuretic	botanical/vegetable herb	II	II	310.545(a)(24)(i)	
AK7JF626KX	senna	digestive aid				310.545(a)(8)(ii)	
AK7JF626KX	senna fluidextract	laxative			I/IIIS		
S8SJ19N2NX	senna pod concentrate	laxative			I/IIIS		
	senna syrup	laxative			I/IIIS		
	sennosides a and b	laxative			I		
7Y1255HVXR	sesame seed	weight control			II	310.545(a)(20)	
4B24275HEU	shark liver oil	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
4B24275HEU	shark liver oil	antimicrobial			n/a		
4B24275HEU	shark liver oil	skin protectant	insect bites/stings w/ sales less than \$25,000	I	I	310.545(a)(18)(v)(B)	
4B24275HEU	shark liver oil	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000	I	I	310.545(a)(18)(vi)(B)	
4B24275HEU	shark liver oil	skin protectant	w/ sales less than \$25,000	I	I	310.545(a)(18)(i)(B)	
4B24275HEU	shark liver oil (combination only)	anorectal	protectant	I(e,i)	I(e,i)	346.14(b)(3)	
95IT3W8JZE	silver nitrate	skin protectant	astringent	II		310.545(a)(18)(ii)	
TYU5GP6XGE	simethicone	antiflatulent			I	332.10	
TYU5GP6XGE	simethicone	digestive aid	antiflatulent	III	I		[58 FR 54454]
TYU5GP6XGE	simethicone	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
TYU5GP6XGE	simethicone	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
	sodium	weight control			II	310.545(a)(20)	
25K35WQ32Q	sodium 3, 4-dimethylphenyl-glyoxylate	sunscreen		II	I		[64 FR 27682]
	sodium acetylsalicylate (in solution)	overindulgence in alcohol	hangover reliever		I		
	sodium aluminum chlorohydroxy lactate	antiperspirant		II			
OJ245FE5EU	sodium benzoate	menstrual/diuretic		II		310.545(a)(4)(i)	
8MDF5V39QO	sodium bicarbonate	antacid			I	310.545(a)(24)(i)	
8MDF5V39QO	sodium bicarbonate	anticaries		II	II		
8MDF5V39QO	sodium bicarbonate	digestive aid	antacid	III	I	331.11(k)(1)	
8MDF5V39QO	sodium bicarbonate	external analgesic			n/a		
8MDF5V39QO	sodium bicarbonate	gingivitis/plaque			III		
8MDF5V39QO	sodium bicarbonate	oral health care	wound cleansing	I	I		
8MDF5V39QO	sodium bicarbonate	skin protectant			I	NA	
8MDF5V39QO	sodium bicarbonate	weight control			III	347.10(o)	
91MBZ8H3QO	sodium borate	acne		II	II	310.545(a)(22)(ii)	
91MBZ8H3QO	sodium borate	antifungal			III		
91MBZ8H3QO	sodium borate	dandruff			II	310.545(a)(7)	
91MBZ8H3QO	sodium borate	external analgesic	insect bite/sting			I	
91MBZ8H3QO	sodium borate	oral health care			III	310.545(a)(10)(vi)	
91MBZ8H3QO	sodium borate	skin protectant	astringent		II		
91MBZ8H3QO	sodium borate	skin protectant	insect bites/stings			II	
91MBZ8H3QO	sodium borate monohydrate	oral health care			III	310.545(a)(18)(ii)	
LC1V549NOM	sodium bromide	daytime sedative			II	III	
LC1V549NOM	sodium bromide	nighttime sleep aid	bromide			I	[54 FR 6826]
9XTM81VK2B	sodium caprylate	antifungal		II		310.545(a)(22)(i)	
9XTM81VK2B	sodium caprylate	oral health care			III		
45P3261C7T	sodium carbonate	antacid			II		
45P3261C7T	sodium carbonate	anticaries			III	331.11(k)(1)	
	sodium carboxymethylcellulose	antidiarrheal			II		
	sodium carboxymethylcellulose	laxative	bulk laxative		I	310.545(a)(2)(i)	
7473P66J9E	sodium caseinate	weight control			III		
451W47IQ8X	sodium chloride	digestive aid			II	310.545(a)(20)	
					I		

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
451W47IQ8X	sodium chloride	ophthalmic	hypertonic agent	I	I	349.16	
451W47IQ8X	sodium chloride (salt)	weight control			II	310.545(a)(20)	
1Q73Q2JULR	sodium citrate	cough/cold	expectorant		III	310.545(a)(6)(iii)	
1Q73Q2JULR	sodium citrate	digestive aid	antacid	III	I	310.545(a)(8)(i)	
1Q73Q2JULR	sodium citrate	relief of oral discomfort			IIIE		
1Q73Q2JULR	sodium citrate in solution	overindulgence in alcohol/hangover reliever/overindulgence			I		
26WJH3CS0B	sodium diacetate	skin protectant	astringent			310.545(a)(18)(ii)	
	sodium dichromate	oral health care				IISE	
3980JIH2SW	sodium dihydrogen phosphate	anticaries		II	NC	310.545(a)(2)(ii)	
	sodium dihydrogen phosphate monohydrate	anticaries		II	NC	310.545(a)(2)(ii)	
8ZYQ1474W7	sodium fluoride	relief of oral discomfort			III		
8ZYQ1474W7	sodium fluoride	relief of oral discomfort			IISE		
8ZYQ1474W7	sodium fluoride (aqueous)	anticaries		I/NC	I	355.10(a)(3)(iii)-(v)	
8ZYQ1474W7	sodium fluoride (aqueous) (acidulated phosphate fluoride with .01% f	anticaries		NC	I		
8ZYQ1474W7	sodium fluoride (aqueous) (acidulated phosphate fluoride with .02% f	anticaries		I	I		
8ZYQ1474W7	sodium fluoride gel or paste	anticaries	dentifrices	I	I	355.10(a)(1)	
8ZYQ1474W7	sodium fluoride powder	anticaries	dentifrices	I	I	355.10(a)(2)	
C810JCZ56Q	sodium monofluorophosphate	anticaries				310.545(a)(2)(i)	
C810JCZ56Q	sodium monofluorophosphate (rinse)	anticaries		II	II		
C810JCZ56Q	sodium monofluorophosphate	relief of oral discomfort			III		
C810JCZ56Q	sodium monofluorophosphate (gel or paste)	anticaries	dentifrices	I	I	355.10(b)(1)	
C810JCZ56Q	sodium monofluorophosphate (gel or paste)	anticaries	dentifrices		I	355.10(b)(2)	
8M4L3H2ZVZ	sodium nitrate	menstrual/diuretic				310.545(a)(24)(i)	
399SL044HN	sodium oleate	laxative	stimulant laxative		III	310.545(a)(12)(iv)(A)	
75UI7QUZ5J	sodium para-aminobenzoate	internal analgesic		II	II	310.545(a)(23)(i)	
Y52BK1W96C	sodium perborate	oral health care			IISE		
Y9UKD0XE6F	sodium perborate monohydrate	oral health care	wound cleansing	II	I		
SE337SVY37	sodium phosphate	anticaries		II	NC	310.545(a)(2)(i)	
SE337SVY37	sodium phosphate	anticaries		II	NC	310.545(a)(2)(ii)	
SE337SVY37	sodium phosphate, dibasic	laxative	saline laxative		I		
SE337SVY37	sodium phosphate, monobasic	laxative	saline laxative		I		
QH257BPV3J	sodium potassium tartrate	antacid			I	331.11(j)(2)	
QH257BPV3J	sodium potassium tartrate	antacid			I	331.11(k)(2)	
DK6Y9P42IN	sodium propionate	antifungal		III	III	310.545(a)(22)(ii)	
DK6Y9P42IN	sodium propionate	antimicrobial			IISE		
WIQ1H85SYP	sodium salicylate	dandruff		III	III	310.545(a)(7)	
WIQ1H85SYP	sodium salicylate	digestive aid				310.545(a)(8)(ii)	
WIQ1H85SYP	sodium salicylate	internal analgesic		I	I		
WIQ1H85SYP	sodium salicylate	menstrual/diuretic	analgesic	I			
WIQ1H85SYP	sodium salicylate	overindulgence in alcohol/food			I		
WIQ1H85SYP	sodium salicylic acid phenolate	anorectal	antiseptic	II(e,i)	II(e,i)	310.545(a)(26)(ii)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
C02T02993U	sodium sulfide (aqueous)	ingrown toenail	gel vehicle		I	538.31	
HX1032V43M	sodium thiosulfate	acne		II	II	310.545(a)(1)	
451IFR0GXB	soopamine hydrobromide	antiemetic			III		
506T60A25R	sorbitol	digestive aid		II	II	310.545(a)(8)(i)	
506T60A25R	sorbitol	laxative	hyperosmotic		I		
506T60A25R	sorbitol	oral health care	demulcents	III		310.545(a)(14)	
	soy meal	weight control		II		310.545(a)(20)	
241ATL177A	soybean oil, hydrogenated (powder)	cholecystokinetic				357.210(b)	
R44IWB3RN5	soybean protein	weight control		II		310.545(a)(20)	
3629601H5D	squill preparations (squill, squill extract)	cough/cold	expectorant		II	310.545(a)(6)(iii)	
3FTR44B32Q	stannous fluoride	anticaries	dentifrices	I	I	355.10(c)(1)(i)	
3FTR44B32Q	stannous fluoride	anticaries	dentifrices	I	I	355.10(c)(1)(ii)	
3FTR44B32Q	stannous fluoride	relief of oral discomfort			IIIIE		
3FTR44B32Q	stannous fluoride (gel)	anticaries		I	I	355.10(c)(2)	
3FTR44B32Q	stannous fluoride (rinse)	anticaries		I	I	355.10(c)(3)	
	stannous pyrophosphate and zinc citrate	gingivitis/plaque			IIIIE		
2KR89I4H1Y	stearyl alcohol	skin protectant	insect bites/stings w/ sales less than \$25,000			310.545(a)(18)(v)(B)	
2KR89I4H1Y	stearyl alcohol	skin protectant	poison ivy/oak/sumac w/ sales less than \$25,000			310.545(a)(18)(vi)(B)	
2KR89I4H1Y	stearyl alcohol	skin protectant	w/ sales less than \$25,000			310.545(a)(18)(i)(B)	
ZLM4P8929R	stem bromelain	digestive aid				310.545(a)(8)(ii)	
4J2TY8Y81V	strawberry	digestive aid				310.545(a)(8)(ii)	
5R78837D4A	strontium chloride	relief of oral discomfort			IIIIE		
5R78837D4A	strontium chloride	relief of oral discomfort			IISE		
H9Y79VD43J	strychnine	digestive aid				310.545(a)(8)(ii)	
70FD1KFU70	sublimed sulfur	anorectal	keratolytic	III(e),II(i)	III(e),II(i)	310.545(a)(26)(v)	
C151H8M554	sucrose	menstrual/diuretic				310.545(a)(24)(i)	
C151H8M554	sucrose	weight control			II	310.545(a)(20)	
	sugars	oral health care	demulcents		III	310.545(a)(14)	
4NRT660KJQ	sulfacetamide sodium	ophthalmic	anti-infective	II	II		
	sulferated oils of turpentine	menstrual/diuretic				310.545(a)(24)(i)	
70FD1KFU70	sulfur	acne		I	I	333.310(e)	
70FD1KFU70	sulfur	antifungal		III		310.545(a)(22)(ii)	
70FD1KFU70	sulfur	dandruff	dandruff	I	I	358.710(a)(7)	
70FD1KFU70	sulfur	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
70FD1KFU70	sulfur	skin protectant	diaper rash		II	310.545(a)(18)(iii)	
70FD1KFU70	sulfur	skin protectant	fever blister/cold sore	II	II	310.545(a)(18)(iv)	
70FD1KFU70	sulfur	skin protectant		II	II	310.545(a)(18)(i)(A)	
70FD1KFU70	sulfur (when combined w/ resorcinol, resocinol monoacetate)	acne		I	I	333.310(f)	
70FD1KFU70	sulfur, sublimed	pediculicide		II	II	310.545(a)(25)(i)	
1W6L629B4K	sulisobenzene	sunscreen		I	I	352.10(o)	
7SEV7J4R1U	talc	skin protectant	astringent	II		310.545(a)(18)(ii)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
7SEV7J4R1U	talc	skin protectant	astringent	II	I	310.545(a)(18)(ii)	
7SEV7J4R1U	talc	skin protectant	diaper rash				
28F9E0DJY10	tannic acid	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
28F9E0DJY11	tannic acid	skin protectant	diaper rash		II	310.545(a)(18)(iii)	
28F9E0DJY12	tannic acid	skin protectant	fever blister/cold sore	II	II	310.545(a)(18)(iv)	
28F9E0DJY13	tannic acid	skin protectant	poison ivy/oak/sumac	II	II	310.545(a)(18)(vi)(A)	
28F9E0DJY14	tannic acid	skin protectant	diaper rash	II	II	310.545(a)(18)(iii)	
28F9E0DJY14	tannic acid	skin protectant	wound healing	II	II	310.545(a)(18)(i)(A)	
28F9E0DJY6	tannic acid	anorectal	astringent	II(e,i)	II(e,i)	310.545(a)(26)(iii)	
28F9E0DJY7	tannic acid	antifungal		II		310.545(a)(22)(ii)	
28F9E0DJY8	tannic acid	digestive aid				310.545(a)(8)(ii)	
28F9E0DJY9	tannic acid	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
28F9E0DJY15	tannic acid glycerite	skin protectant	astringent	II		310.545(a)(18)(ii)	
	taraxacum officinale	menstrual/diuretic	botanical/vegetable herb	II	II	310.545(a)(24)(i)	
W4888I119H	tartaric acid	laxative	saline laxative			310.545(a)(12)(ii)	
	tartrate (acid or salt)	antacid			I	331.11(m)	
	terpin hydrate prearations (terpin hydrate, terpin hydrate elixer)	cough/cold	expectorant		III	310.545(a)(6)(iii)	
0619F35CGV	tetracaine	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(h)	
0619F35CGV	tetracaine	external analgesic	analgesic & anesthetic	I	I	pending	
0619F35CGV	tetracaine	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
5NF5D4OPCI	tetracaine hydrochloride	acne		II	II	310.545(a)(1)	
5NF5D4OPCI	tetracaine hydrochloride	anorectal	local anesthetic	III(e,i)	I(e),III(i)	346.10(i)	
5NF5D4OPCI	tetracaine hydrochloride	external analgesic		I	I		
5NF5D4OPCI	tetracaine hydrochloride	oral health care	anesthetic/analgesic	II	II	310.545(a)(14)	
5NF5D4OPCI	tetracycline hydrochloride	first aid antibiotic	ointment		I	333.110(f)	
0YZT43HS7D	tetrahydrozoline hydrochloride	ophthalmic	vasoconstrictor	I	I	349.18(d)	
M572600E5P	thiamine hydrochloride (vitamin B1)	weight control			II	310.545(a)(20)	
8K0I04919X	thiamine mononitrate (vitamine B1 mononitrate)	weight control			II	310.545(a)(20)	
7ZQC1892H9	thenyldiamine hydrochloride	cough/cold	antihistamine	III	III	310.545(a)(6)(i)	
7ZQC1892H9	thenyldiamine hydrochloride	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
7ZQC1892H9	thenyldiamine hydrochloride	cough/cold	nasal decongestant	III	III		[59 FR 43408]
	theobromine sodium salicylate	menstrual/diuretic	antihistamine	III	III	310.545(a)(24)(i)	
C137DTR5RG	theophylline	menstrual/diuretic	antihistamine	III	III	310.545(a)(24)(i)	
C137DTR5RG	theophylline (in combination)	cough/cold	bronchodilator			310.545(a)(6)(iv)(B)	
	theophylline calcium salicylate	cough/cold	bronchodilator	I	II	310.545(a)(6)(iv)	
	theophylline sodium glycinate	cough/cold	bronchodilator	I	II	310.545(a)(6)(iv)	
0I55128JYK	theophylline, anhydrous	cough/cold	bronchodilator	I	II	310.545(a)(6)(iv)	
M572600E5P	thiamine hydrochloride	menstrual/diuretic				310.545(a)(24)(i)	
M572600E5P	thiamine hydrochloride	nighttime sleep aid		II	II		
2225PI3MOV	thimerosal	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
	thiocyanacetate	pediculicide		II	II	310.545(a)(25)(i)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
6K9YKD48Y4	thonzylamine hydrochloride	cough/cold	antihistamine	I	I	341.12(l)	
2ZD004190S	threonine	weight control			II	310.545(a)(20)	
3J50XA376E	thymol	acne		II	III	310.545(a)(1)	
3J50XA376E	thymol	antifungal		II		310.545(a)(22)(ii)	
3J50XA376E	thymol	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
3J50XA376E	thymol	dandruff		III	III	310.545(a)(7)	
3J50XA376E	thymol	external analgesic	analgesic & anesthetic	III	III	310.545(a)(10)(i)	
3J50XA376E	thymol	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
3J50XA376E	thymol	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
3J50XA376E	thymol	oral health care	anesthetic/analgesic	III	III	310.545(a)(14)	
3J50XA376E	thymol	relief of oral discomfort			IIIIE		
3J50XA376E	thymol	relief of oral discomfort			IIIIE		
3J50XA376E	thymol	skin protectant	astringent	II		310.545(a)(18)(ii)	
3J50XA376E	thymol (lozenge)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
3J50XA376E	thymol (mouthwash)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
3J50XA376E	thymol iodide	oral health care			IIIIE		
3J50XA376E	thymol iodide	relief of oral discomfort			IIIIE		
3J50XA376E	thymol iodide	relief of oral discomfort			IIIIE		
15FIX9V2JP	titanium dioxide	sunscreen		I	I	352.10(p)	
5236RK32KG	tolindate	antifungal		II	II	310.545(a)(22)(ii)	
06KB629TKV	tolnaftate	antifungal		I	I	333.210(e)	
TD2LE91MBE	tolu balsam	oral health care		III			
TD2LE91MBE	tolu preparations (tolu, tolu balsalm, tolu balsalm tincture)	cough/cold	expectorant		III	310.545(a)(6)(iii)	
08232NY3SJ	topical starch	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(9)	
O8232NY3SJ	topical starch	external analgesic			IISE		
O8232NY3SJ	topical starch	skin protectant	astringent	II		310.545(a)(18)(ii)	
O8232NY3SJ	topical starch	skin protectant	diaper rash		I		
O8232NY3SJ	topical starch	skin protectant	fever blister/cold sore			310.545(a)(18)(iv)	
O8232NY3SJ	topical starch	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
O8232NY3SJ	topical starch	skin protectant		I		347.10(q)	
O8232NY3SJ	topical starch	skin protectant			IISE	310.545(a)(18)(iv)	
XHX3C3X673	triacetin	antifungal		III	III	310.545(a)(22)(ii)	
K4C08XP666	tricalcium phosphate	antacid				331.11(i)(3)	
K4C08XP666	tricalcium phosphate	weight control		II		310.545(a)(20)	
BGG1Y1ED0Y	triclocarban	antimicrobial			IIIIE		
BGG1Y1ED0Y	triclocarban	antimicrobial			IIISE		
BGG1Y1ED0Y	triclocarban	antimicrobial			IIISE		
BGG1Y1ED0Y	triclocarban	antimicrobial			IIISE		
BGG1Y1ED0Y	triclocarban	antimicrobial			IISE		
BGG1Y1ED0Y	triclocarban	antimicrobial			IISE		
BGG1Y1ED0Y	triclocarban	antimicrobial			IISE		

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
BGG1Y1ED0Y	triclocarban	antimicrobial			I		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	triclosan	antimicrobial			III		
4NM5039Y5X	trillium	digestive aid				310.545(a)(8)(ii)	
FWV8GJ56ZN	tripelennamine hydrochloride	external analgesic	fever blister/cold sore	I		310.545(a)(10)(v)	
FWV8GJ56ZN	tripelennamine hydrochloride	external analgesic		I			
	triple dye	antimicrobial			III		
	triple dye	antimicrobial			III		
	triple dye	antimicrobial			III		
	triple dye	antimicrobial			II		
	triple dye	antimicrobial			II		
	triple dye	antimicrobial			II		
	triple dye	antimicrobial			II		
	triple dye	antimicrobial			II		
	triple dye	antimicrobial			II		
	triple dye	antimicrobial			II		
YAN7R5L890	triprolidine hydrochloride	cough/cold	antihistamine	I		341.12(m)	
8K1MK5E1FY	triticum	menstrual/diuretic		II	II	310.545(a)(24)(i)	
9O3K93S3TK	trolamine	external analgesic			III		
9O3K93S3TK	trolamine	skin protectant	fever blister/cold sore			310.545(a)(18)(iv)	
9O3K93S3TK	trolamine	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
9O3K93S3TK	trolamine	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
H8O4040BHD	trolamine salicylate	sunscreen		I	I	352.10(q)	
H8O4040BHD	trolamine salicylate (triethanolamine salicylate)	external analgesic	fever blister/cold sore	III	III	310.545(a)(10)(v)	
H8O4040BHD	trolamine salicylate (triethanolamine salicylate)	external analgesic	insect bite/sting	III	III	310.545(a)(10)(vi)	
H8O4040BHD	trolamine salicylate (triethanolamine salicylate)	external analgesic	poison ivy/oak/sumac	III	III	310.545(a)(10)(vii)	
8DUH1N11BX	tryptophan	weight control			II	310.545(a)(20)	
XJ6RUH0O4G	turpentine oil	external analgesic	fever blister/cold sore	I	I	310.545(a)(10)(v)	
XJ6RUH0O4G	turpentine oil	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
XJ6RUH0O4G	turpentine oil	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
XJ6RUH0O4G	turpentine oil	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
XJ6RUH0O4G	turpentine oil	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
XJ6RUH0O4G	turpentine oil (oral)	cough/cold	antitussive	III	III		
XJ6RUH0046	turpentine oil (rectified)	anorectal	counterirritant	II(e,i)	II(e,i)	310.545(a)(26)(iv)	
XJ6RUH0O4G	turpentine oil (spirits of turpentine)	cough/cold	expectorant			310.545(a)(6)(iii)	
XJ6RUH0O4G	turpentine oil (spirits of turpentine) (oral)	cough/cold	nasal decongestant	II	II	310.545(a)(6)(ii)(A)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
XJ6RUH0O4G	turpentine oil (spirits of turpentine) (topical)	cough/cold	nasal decongestant	III	III	310.545(a)(6)(ii)(A)	
XJ6RUH0O4G	turpentine oil (topical/inhalant)	cough/cold	antitussive	III	IIIIE		[52 FR 30055]
AD8LJ73GQF	turpentine, venice (venice turpentine)	menstrual/diuretic				310.545(a)(24)(i)	
42HK56048U	tyrosine	weight control			II	310.545(a)(20)	
	undecylium chlorideiodine complex	antimicrobial			IIIIE		
	undecylium chlorideiodine complex	antimicrobial			IIISE		
	undecylium chlorideiodine complex	antimicrobial			IIISE		
	undecylium chlorideiodine complex	antimicrobial			IIISE		
	undecylium chlorideiodine complex	antimicrobial			IIISE		
	undecylium chlorideiodine complex	antimicrobial			IIISE		
	undecylium chlorideiodine complex	antimicrobial			IIISE		
K3D86KJ24N	undecylenic acid	antifungal		I	I	333.210(f)	
K3D86KJ24N	undecylenic acid	dandruff		III	III	310.545(a)(7)	
8W8T17847W	urea	menstrual/diuretic				310.545(a)(24)(i)	
3M5V3D1X36	uva ursi, extract of	menstrual/diuretic		II	II		
	uva ursi, potassium extract	weight control			II	310.545(a)(20)	
HG18B9YRS7	valine	weight control			II	310.545(a)(20)	
9ZP99WL196	vegetable (green)	weight control			II	310.545(a)(20)	
81G40H8B0T	vitamin A	anorectal	wound healing	III(e,i)	III(e,i)	310.545(a)(26)(x)	
81G40H8B0T	vitamin A	corn/callus remover		II	IISE		[55 FR 33261]
81G40H8B0T	vitamin A	skin protectant	diaper rash		IIISE		
81G40H8B0T	vitamin A	weight control			II	310.545(a)(20)	
	vitamin A acetate	weight control			II	310.545(a)(20)	
	vitamin A palmitate	weight control			II	310.545(a)(20)	
H4N855PNZ1	vitamin E	acne		II	II	310.545(a)(1)	
H4N855PNZ1	vitamin E	nighttime sleep aid			II		
H4N855PNZ1	vitamin E	stimulant			IIIE		[39 FR 6104]
H4N855PNZ1	vitamin E	weight control			II	310.545(a)(20)	
	vitromersol	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
	water and additives	ophthalmic			I		
059QF0KO0R	water, purified	ophthalmic				349.20	
7G1J5DA97F	wax, white	ophthalmic	emollient	I	I	349.14(b)(7)	
2ZA36H0S2V	wax, yellow	ophthalmic	emollient	NA	I	349.14(b)(8)	
YR3G369F5A	wheat germ	weight control			II	310.545(a)(20)	
	white ointment	ophthalmic	emollient	I	I	349.14(b)(5)	
4T6H12BN9U	white petrolatum	anorectal	protectant	I(e,i)	I(e,i)	346.14(a)(10)	
101I4J0U34	witch hazel	skin protectant	astringent	I	I	347.12(c)	
1014J0U34	witch hazel (haramelis water)	anorectal	astringent	I(e)	I(e)	346.18(b)	
N8C4A9A49H	woodruff	digestive aid				310.545(a)(8)(ii)	
TTV12P4NEE	xanthan gum	weight control			III	310.545(a)(20)	
X5S8403NZ	xylometazoline hydrochloride (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(10)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
X5S84033NZ	xylometazoline hydrochloride (aqueous)	cough/cold	nasal decongestant		I	341.20(b)(10)	
X5S84033NZ	xylometazoline hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(10)	
X5S84033NZ	xylometazoline hydrochloride (jelly)	cough/cold	nasal decongestant	I	I	341.20(b)(10)	
3NY3SM6B8U	yeast	weight control			II	310.545(a)(20)	
3NY3SM6B8U	yeast cell derivative, live	skin protectant	diaper rash		IIIIE		
3NY3SM6B8U	yeast cell derivative, live	skin protectant	wound healing agent		IIISE	310.545(a)(18)(i)(B)	
IY191986AO	yellow mercuric oxide	ophthalmic	anti-infective	III	II	310.545(a)(21)(ii)	
FM5526K07A	zinc acetate	external analgesic			IISE		
FM5526K07A	zinc acetate	skin protectant	diaper rash		III	310.545(a)(18)(iii)	
FM5526K07A	zinc acetate	skin protectant	wound healing agent	I	I	310.545(a)(18)(i)(A)	
FM5526K07A	zinc acetate	skin protectant		I	I	347.10(s)	
QL5435GI2S	zinc caprylate	antifungal		III	III	310.545(a)(22)(ii)	
EQR32Y7H0M	zinc carbonate	skin protectant	diaper rash		III	310.545(a)(18)(iii)	
EQR32Y7H0M	zinc carbonate	skin protectant		I	I	347.10(t)	
86Q357L16B	zinc chloride	corn/callus remover		III	IIIIE		[55 FR 33261]
86Q357L16B	zinc chloride	oral health care		I	I		
86Q357L16B	zinc chloride	skin protectant	astringent	II		310.545(a)(18)(ii)	
K72I3DEX9B	zinc citrate	gingivitis/plaque			IIIIE		
SOI2LOH54Z	zinc oxide	acne		II	II	310.545(a)(1)	
SOI2LOH54Z	zinc oxide	anorectal	astringent	I(e,i)	I(e,i)	346.18(c)	
SOI2LOH54Z	zinc oxide	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
SOI2LOH54Z	zinc oxide	external analgesic			IISE		
SOI2LOH54Z	zinc oxide	n/a			I	352.10(r)	
SOI2LOH54Z	zinc oxide	skin protectant	astringent	II	II	310.545(a)(18)(ii)	
SOI2LOH54Z	zinc oxide	skin protectant		I	I	347.10(u)	
SOI2LOH54Z	zinc oxide	sunscreen			III	352.10(r)	
SOI2LOH54Z	zinc oxide (combination only)	anorectal	protectant	I(e,i)	I(e,i)	346.14(b)(4)	
4O71YT5YB5	zinc phenol sulfonate	sunscreen					[64 FR 27682]
4O71YT5YB5	zinc phenolsulfonate	antidiarrheal		III	III	310.545(a)(3)(i)	
4O71YT5YB5	zinc phenolsulfonate	antiemetic			II		
4O71YT5YB5	zinc phenolsulfonate	skin protectant	astringent	II		310.545(a)(18)(ii)	
	zinc propionate	antifungal		III	III	310.545(a)(22)(ii)	
H92E6QA4FV	zinc stearate	acne		II	II	310.545(a)(1)	
H92E6QA4FV	zinc stearate	skin protectant	astringent	II		310.545(a)(18)(ii)	
89DS0H96TB	zinc sulfate	external analgesic	fever blister/cold sore			310.545(a)(10)(v)	
89DS0H96TB	zinc sulfate	ophthalmic	astringent	I	I	349.10	
89DS0H96TB	zinc sulfate	poison treatment			II	310.545(a)(16)	
89DS0H96TB	zinc sulfate	skin protectant	astringent	II		310.545(a)(18)(ii)	
89DS0H96TB	zinc sulfate	skin protectant	fever blister/cold sore			310.545(a)(18)(iv)	
89DS0H96TB	zinc sulfide	acne		II	II	310.545(a)(1)	
388VZ25DUR	zinc undecylenate	antifungal		I	I	333.210(f)	

UNII Code	Active Ingredient	Monograph	Sub-category	Panel	Pending	Final	FR Citation
	zirconium oxide	external analgesic	insect bite/sting			310.545(a)(10)(vi)	
	zirconium oxide	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
	zirconium oxide	skin protectant	insect bites/stings			310.545(a)(18)(v)(A)	
	zirconium oxide	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	
	zyloxin	antimicrobial	first aid antiseptic			310.545(a)(27)(i)	
	zyloxin	external analgesic	poison ivy/oak/sumac			310.545(a)(10)(vii)	
	zyloxin	skin protectant	poison ivy/oak/sumac			310.545(a)(18)(vi)(A)	